: 4410-09-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. 20-04]
Medical Pharmacy
Decision and Order

On November 18, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC/ISO) to Medical Pharmacy (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of its DEA Certificate of Registration Number AL3398117 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), because Respondent's "continued registration is inconsistent with the public interest." *Id.* (citing 21 U.S.C. §§ 824(a)(4) and 823(f)).

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from May 4-7, 2020, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video teleconference (VTC). On July 2, 2020, Chief Administrative Law Judge John J. Mulrooney, II, (hereinafter, Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). On July 22, 2020, the Respondent filed Exceptions to the Recommended Decision (hereinafter, Resp Exceptions), to which the Government responded on August 7, 2020. Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the Chief ALJ's Recommended Decision with minor modifications, as noted herein.[*A] I have addressed the

[*A] I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where

majority of Respondent's Exceptions in footnotes added to the corresponding parts of the RD, and the remaining exceptions are addressed in "The Respondent's Exceptions" section following the RD. While I have made some modifications to the RD based on the exceptions, none of those changes and none of Respondent's arguments persuaded me to reach a different conclusion than the Chief ALJ in this matter. Therefore, I issue my final Order in this case following the Recommended Decision.

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE [*B]

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that the Respondent's COR should be revoked on the grounds alleged by the Government.[1] After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The Government alleges that the Respondent's COR should be revoked because on numerous occasions between October 2016 and September 2019, it repeatedly filled prescriptions without addressing or resolving factual indicia (*i.e.*, "red flags") of potential drug diversion. ALJ Ex. 1 at 2. According to the Government, this constituted unlawfully reckless and negligent dispensing. ALJ Ex. 1 at 2.

I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun "I" refers to myself—the Administrator.

[*B] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] The immediate suspension aspect of the Government's case was final as of the date the OSC/ISO was issued by the Administrator, and is not the subject of these proceedings. 21 U.S.C. § 824(d)(1) ("A[n immediate] suspension . . . shall continue in effect until the conclusion of [administrative enforcement] proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction."); 21 CFR § 1301.36(h) ("Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.").

The Evidence

Stipulations

The parties entered into factual stipulations prior to and during the litigation of this matter which were accepted by the tribunal. The following factual matters are deemed conclusively established in this case.

1. The Respondent pharmacy is registered with the DEA to handle controlled substances in Schedules II through V under DEA COR number AL3398117. The Respondent pharmacy's registered address is 6400 Main St., P.O. Box 475, Zachary, LA 70791.
2. The Respondent pharmacy's DEA COR expires by its own terms on January 31, 2021.
3. The Respondent pharmacy filled the following prescriptions for Patient C.H.:

    a. 9/12/17: Carisoprodol 350 mg, 120 tablets
    b. 9/12/17: Alprazolam 1 mg, 90 tablets
    c. 9/12/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
    d. 9/12/17: Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets

4. The Respondent pharmacy filled the following prescriptions for Patient J.M.B.:

    a. 6/05/17: Hydromorphone 8 mg, 120 tablets
    b. 6/05/17: Alprazolam 1 mg, 60 tablets
    c. 6/05/17: Carisoprodol 350 mg, 120 tablets
    d. 6/05/17: Morphine SO4 ER 30 mg, 90 tablets
    e. 7/05/17: Alprazolam 1 mg, 60 tablets
    f. 7/05/17: Morphine SO4 ER 30 mg, 90 tablets
    g. 7/05/17: Carisoprodol 350 mg, 120 tablets
    h. 7/05/17: Hydromorphone 8 mg, 120 tablets
    i. 9/14/17: Alprazolam 1 mg, 60 tablets
    j. 9/27/17: Morphine SO4 ER 15 mg, 30 tablets
    k. 9/27/17: Morphine SO4 ER 30 mg, 60 tablets
    l. 9/27/17: Carisoprodol 350 mg 120 tablets
    m. 9/27/17: Hydromorphone 8 mg, 120 tablets
    n. 10/27/17: Carisoprodol 350 mg, 120 tablets
    o. 10/27/17: Hydromorphone 8 mg, 120 tablets
    p. 12/20/17: Carisoprodol 350 mg, 120 tablets
    q. 12/20/17: Alprazolam 1 mg, 50 tablets
    r. 12/20/17: Hydromorphone 8 mg, 120 tablets
    s. 12/21/17: Morphine SO4 ER 30 mg, 60 tablets
    t. 8/16/18: Alprazolam 1 mg, 60 tablets
    u. 8/30/18: Hydromorphone 8 mg, 120 tablets

v. 8/30/18: Carisoprodol 350 mg, 120 tablets
w. 9/10/18: Morphine SO4 ER 30 mg, 60 tablets
x. 9/21/18: Alprazolam 1 mg, 60 tablets
y. 9/27/18: Carisoprodol 350 mg, 120 tablets
z. 9/27/18: Hydromorphone 8 mg, 120 tablets
aa. 10/15/18: Morphine SO4 ER 30 mg, 60 tablets
bb. 10/24/18 : Carisoprodol 350 mg, 120 tablets
cc. 10/24/18: Hydromorphone 8 mg, 120 tablets
dd. 11/13/18: Morphine SO4 ER 30 mg, 60 tablets
ee. 11/27/18: Hydromorphone 8 mg, 120 tablets
ff. 11/27/18: Carisoprodol 350 mg, 120 tablets
gg. 11/29/18: Alprazolam 1 mg, 60 tablets
hh. 12/24/18: Carisoprodol 350 mg, 120 tablets
ii. 12/24/18: Hydromorphone 8 mg, 120 tablets
jj. 12/28/18: Alprazolam 1 mg, 60 tablets
kk. 1/08/19: Morphine SO4 ER 30 mg, 60 tablets
ll. 1/22/19: Hydromorphone 8 mg, 120 tablets
mm. 1/22/19: Carisoprodol 350 mg, 120 tablets
nn. 2/08/19: Alprazolam 1 mg, 60 tablets
oo. 2/08/19: Morphine SO4 ER 30 mg, 60 tablets
pp. 2/19/19: Carisoprodol 350 mg, 120 tablets
qq. 2/19/19: Hydromorphone 8 mg, 120 tablets
rr. 7/01/19: Morphine SO4 ER 30 mg, 60 tablets
ss. 7/08/19: Carisoprodol 350 mg, 120 tablets
tt. 7/08/19: Hydromorphone 8 mg, 120 tablets
uu. 8/05/19: Hydromorphone 8 mg, 120 tablets
vv. 8/05/19: Carisoprodol 350 mg, 120 tablets
ww. 8/20/19: Alprazolam 1 mg, 60 tablets
xx. 8/27/19: Hydromorphone 8 mg, 120 tablets
yy. 8/27/19: Carisoprodol 350 mg, 120 tablets

5. The Respondent pharmacy filled the following prescriptions for Patient T.D.:

a. 7/13/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets
b. 8/08/17: Clonazepam 0.5 mg, 60 tablets
c. 8/08/17: Carisoprodol 350 mg, 60 tablets
d. 8/12/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets
e. 7/11/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets
f. 7/18/18: Clonazepam 0.5 mg, 60 tablets
g. 7/18/18: Carisoprodol 350 mg, 60 tablets

6. The Respondent pharmacy filled the following prescriptions for Patient D.G.:

a. 2/10/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
b. 2/10/17: Carisoprodol 350 mg, 30 tablets
c. 2/21/17: Diazepam 10 mg, 60 tablets
d. 3/09/17: Carisoprodol 350 mg, 30 tablets
e. 3/09/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
f. 3/21/17: Diazepam 10 mg, 60 tablets
g. 4/06/17: Carisoprodol 350 mg, 30 tablets
h. 4/06/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
i. 4/26/17: Diazepam 10 mg, 60 tablets

j. 5/04/17: Carisoprodol 350 mg, 30 tablets
k. 5/04/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
l. 5/30/17: Diazepam 10 mg, 60 tablets
m. 6/01/17: Carisoprodol 350 mg, 30 tablets
n. 6/01/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
o. 6/29/17: Diazepam 10 mg, 60 tablets
p. 6/29/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
q. 6/29/17: Carisoprodol 350 mg, 30 tablets
r. 7/27/17: Carisoprodol 350 mg, 30 tablets
s. 7/27/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
t. 7/28/17: Diazepam 10 mg, 60 tablets
u. 8/23/17: Diazepam 10 mg, 60 tablets
v. 8/24/17: Carisoprodol 350 mg, 30 tablets
w. 8/27/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
x. 9/21/17: Carisoprodol 350 mg, 30 tablets
y. 9/21/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
z. 9/25/17: Diazepam 10 mg, 60 tablets
aa. 11/16/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
bb. 11/16/17: Carisoprodol 350 mg, 30 tablets
cc. 11/20/17: Diazepam 10 mg, 60 tablets
dd. 12/14/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
ee. 12/14/17: Carisoprodol 350 mg, 30 tablets
ff. 12/14/17: Diazepam 10 mg, 60 tablets
gg. 1/12/18: Carisoprodol 350 mg, 30 tablets
hh. 1/12/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
ii. 1/24/18: Diazepam 10 mg, 60 tablets
jj. 2/09/18: Carisoprodol 350 mg, 30 tablets
kk. 2/09/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
ll. 2/21/18: Diazepam 10 mg, 60 tablets
mm. 3/09/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
nn. 3/09/18: Carisoprodol 350 mg, 30 tablets
oo. 3/26/18: Diazepam 10 mg, 60 tablets
pp. 6/06/18: Carisoprodol 350 mg, 30 tablets
qq. 6/06/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
rr. 6/14/18: Diazepam 10 mg, 60 tablets
ss. 7/05/18: Carisoprodol 350 mg, 30 tablets
tt. 7/05/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
uu. 7/16/18: Diazepam 10 mg, 60 tablets
vv. 8/02/18: Carisoprodol 350 mg, 30 tablets
ww. 8/02/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
xx. 8/13/18: Diazepam 10 mg, 60 tablets
yy. 8/30/18: Carisoprodol 350 mg, 30 tablets
zz. 8/30/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
aaa. 9/08/18: Diazepam 10 mg, 60 tablets
bbb. 10/26/18: Carisoprodol 350 mg, 30 tablets
ccc. 10/26/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
ddd. 11/06/18: Diazepam 10 mg, 60 tablets

7. The Respondent pharmacy filled the following prescriptions for Patient J.H.:

a. 2/07/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 45 tablets
b. 2/07/17: Diazepam 10 mg, 18 tablets
c. 2/07/17: Zolpidem Tartrate 10 mg, 30 tablets
d. 2/09/17: Carisoprodol 350 mg, 90 tablets
e. 7/13/17: Diazepam 10 mg, 90 tablets
f. 7/13/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 40 tablets
g. 7/13/17: Carisoprodol 350 mg, 120 tablets
h. 7/31/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 40 tablets
i. 8/11/17: Diazepam 10 mg, 90 tablets
j. 8/11/17: Carisoprodol 350 mg, 120 tablets
k. 9/29/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets
l. 10/10/17: Carisoprodol 350 mg, 120 tablets
m. 10/11/17: Diazepam 10 mg, 90 tablets
n. 10/26/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
o. 4/26/18: Carisoprodol 350 mg, 120 tablets
p. 4/26/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets
q. 4/26/18: Diazepam 10 mg, 35 tablets
r. 5/24/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets
s. 5/24/18: Carisoprodol 350 mg, 120 tablets
t. 5/24/18: Diazepam 10 mg, 35 tablets
u. 9/20/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets
v. 9/20/18: Carisoprodol 350 mg, 120 tablets
w. 9/20/18: Diazepam 10 mg, 35 tablets
x. 10/18/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
y. 10/18/18: Carisoprodol 350 mg, 120 tablets
z. 10/18/18: Diazepam 10 mg, 35 tablets

8. The Respondent pharmacy filled the following prescriptions for Patient R.I.:

a. 8/17/17: Alprazolam 1 mg, 120 tablets
b. 8/25/17: Zolpidem Tartrate 10 mg, 30 tablets
c. 8/25/17: Carisoprodol 350 mg, 30 tablets
d. 8/25/17: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets
e. 9/11/17: Alprazolam 1 mg, 120 tablets
f. 9/25/17: Carisoprodol 350 mg, 30 tablets
g. 9/25/17: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets
h. 10/12/17: Alprazolam 1 mg, 120 tablets
i. 10/25/17: Carisoprodol 350 mg, 30 tablets
j. 10/25/17: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets
k. 11/13/17: Zolpidem Tartrate 10 mg, 30 tablets
l. 11/13/17: Alprazolam 1 mg, 120 tablets
m. 11/24/17: Carisoprodol 350 mg, tablets 30
n. 11/24/17: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets
o. 12/09/17: Zolpidem Tartrate 10 mg, 30 tablets
p. 12/13/17: Alprazolam 1 mg, 120 tablets
q. 12/23/17: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets
r. 12/27/17: Carisoprodol 350 mg, 30 tablets
s. 08/15/18: Alprazolam 1 mg, 90 tablets
t. 08/24/18: Carisoprodol 350 mg, 30 tablets
u. 08/24/18: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets

v. 11/08/18: Alprazolam 1 mg, 90 tablets
w. 11/23/18: Zolpidem Tartrate 10 mg, 30 tablets
x. 11/24/18: Carisoprodol 350 mg, 30 tablets
y. 11/24/18: Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets
z. 12/06/18: Alprazolam 1 mg, 90 tablets
aa. 12/24/18: Oxycodone-Acetaminophen 10 mg/325 mg , 30 tablets
bb. 12/24/18: Hydrocodone-Acetaminophen 5 mg/325 mg, 10 tablets
cc. 12/24/18: Carisoprodol 350 mg, 30 tablets
dd. 01/04/19: Alprazolam 1 mg, 90 tablets

9. The Respondent pharmacy filled the following prescriptions for Patient J.B.:

a. 7/02/19: Dextroamphetamine-Amphetamine 20 mg, 90 tablets
b. 7/02/19: Alprazolam 0.5 mg, 60 tablets
c. 7/02/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets

10. The Respondent pharmacy filled the following prescriptions for Patient P.W.:

a. 4/04/19: Alprazolam 0.5 mg, 60 tablets
b. 4/04/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 30 tablets
c. 8/01/19: Alprazolam 0.5 mg, 60 tablets
d. 8/01/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 30 tablets
e. 8/29/19: Alprazolam 0.5 mg, 60 tablets
f. 8/29/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 30 tablets

11. The Respondent pharmacy filled the following prescriptions for Patient L.H.:

a. 6/14/17: Alprazolam 1 mg, 360 tablets
b. 6/22/17: Dextroamphetamine-Amphetamine 30 mg, 30 tablets
c. 6/22/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 20 tablets

12. The Respondent pharmacy filled the following prescriptions for Patient A.P.:

a. 8/02/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 25 tablets
b. 8/02/17: Zolpidem Tartrate 10 mg, 30 tablets

13. The Respondent pharmacy filled the following prescriptions for Patient M.A.:

a. 10/12/17: Alprazolam 1 mg, 30 tablets
b. 10/12/17: Dextroamphetamine-Amphetamine 30 mg, 60 tablets
c. 10/12/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets

14. The Respondent pharmacy filled the following prescriptions for Patient B.B.:

a. 10/19/17: Alprazolam 1 mg, 90 tablets
b. 10/19/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets
c. 1/11/17: Alprazolam 0.5 mg, 2 tablets
d. 1/11/17: Diazepam 10 mg, 2 tablets
e. 1/12/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets
f. 2/08/17: Alprazolam 0.5 mg, 2 tablets
g. 2/08/17: Diazepam 10 mg, 2 tablets

h. 2/10/17: Alprazolam 0.5 mg, 60 tablets
i. 2/10/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets
j. 3/09/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets
k. 3/09/17: Alprazolam 0.5 mg, 60 tablets
l. 5/04/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets

15. The Respondent pharmacy filled the following prescriptions for Patient T.D.:

a. 3/07/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets
b. 3/07/18: Clonazepam 0.5 mg, 60 tablets

16. The Respondent pharmacy filled the following prescriptions for Patient L.D.:

a. 8/19/19: Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets
b. 8/19/19: Lorazepam 0.5 mg, 60 tablets
c. 8/19/19: Morphine SO4 ER 30 mg, 60 tablets

17. The Respondent pharmacy filled the following prescriptions for Patient R.W.:

a. 8/12/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
b. 8/12/19: Diazepam 5 mg, 30 tablets
c. 9/09/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
d. 9/09/19: Diazepam 5 mg, 30 tablets

18. The Respondent pharmacy filled the following prescriptions for Patient L.C.:

a. 3/21/19: Oxycodone-Acetaminophen 7.5 mg/325 mg, 14 tablets
b. 3/21/19: Oxycodone-Acetaminophen 7.5 mg/325 mg, 16 tablets

19. The Respondent pharmacy filled the following prescriptions for Patient K.W.:

a. 4/16/19: Alprazolam 0.25 mg, 60 tablets
b. 4/16/19: Dextroamphetamine-Amphetamine 20 mg, 90 tablets

20. The Respondent pharmacy filled the following prescriptions for Patient D.M.:

a. 6/08/17: Alprazolam 1 mg, 60 tablets
b. 6/08/17: Dextroamphetamine-Amphetamine 30 mg, 60 tablets

21. The Respondent pharmacy filled the following prescriptions for Patient K.S.:

a. 6/26/17: Dextroamphetamine-Amphetamine 30 mg, 60 tablets
b. 6/26/17: Oxycodone-Acetaminophen 10 mg/325 mg, 60 tablets

22. The Respondent pharmacy filled the following prescription for Patient P.B.:

a. 6/26/19: Methadone 10 mg, 60 tablets
b. 6/29/19: Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets

23. The Respondent pharmacy filled the following prescriptions for Patient C.S.:

a. 6/11/19: Oxycodone 30 mg, 90 tablets

b. 7/09/19: Oxycodone 30 mg, 90 tablets

24. The Respondent pharmacy filled the following prescriptions for Patient S.N.:

a. 6/05/19: Hydrocodone-Acetaminophen 7.5 mg/325 mg, 30 tablets
b. 6/19/19: Hydrocodone-Acetaminophen 7.5 mg/325 mg, 60 tablets

25. The Respondent pharmacy filled the following prescriptions for Patient P.R.:

a. 10/24/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 112 tablets
b. 6/13/19: Hydrocodone-Acetaminophen 10 mg/325 mg, 112 tablets

26. The Respondent pharmacy filled the following prescriptions for Patient D.F.:

a. 6/04/19: Alprazolam 0.5 mg, 120 tablets
b. 6/04/19: Dextroamphetamine-Amphetamine 30 mg, 60 tablets
c. 6/04/19: Butalbital-Acetaminophen-Caffeine 50 mg/325 mg/40 mg, 60 tablets

27. The Respondent pharmacy filled the following prescriptions for Patient D.L.:

a. 8/09/17: Diazepam 10 mg, 90 tablets
b. 8/09/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets

28. The Respondent pharmacy filled the following prescriptions for Patient M.L.:

a. 8/02/17: Diazepam 10 mg, 45 tablets

29. The Respondent pharmacy filled the following prescriptions for Patient K.C.:

a. 10/09/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 75 tablets
b. 10/09/17: Alprazolam 1 mg, 60 tablets

30. The Respondent pharmacy filled the following prescriptions for Patient G.C.:

a. 10/10/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
b. 10/10/17: Alprazolam 1 mg, 90 tablets

31. The Respondent pharmacy filled the following prescriptions for Patient V.M.:

a. 10/20/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
b. 10/20/17: Alprazolam 1 mg, 60 tablets

32. The Respondent pharmacy filled the following prescriptions for Patient A.G.:

a. 9/06/16: Oxycodone 15 mg, 90 tablets
b. 6/27/19: Oxycodone 15 mg, 120 tablets
c. 7/24/19: Oxycodone 15 mg, 120 tablets
d. 8/22/19:, Oxycodone 15 mg, 120 tablets

33. The Respondent pharmacy filled the following prescriptions for Patient T.B.:

    a. 5/22/17: Oxycodone 15 mg, 90 tablets
    b. 6/25/18: Oxycodone 15 mg, 60 tablets
    c. 7/09/18: Oxycodone 15 mg, 60 tablets
    d. 7/23/18: Oxycodone 15 mg, 60 tablets

34. The Respondent pharmacy filled the following prescriptions for Patient K.R.:

    a. 4/09/18: Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets
    b. 8/04/18: Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets

35. The Respondent pharmacy filled the following prescriptions for Patient L.W.:

    a. 7/27/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
    b. 7/27/17: Alprazolam 1 mg, 90 tablets
    c. 7/27/17: Dextroamphetamine-Amphetamine 20 mg, 60 tablets
    d. 7/27/17: Phentermine 37.5 mg, 30

36. The Respondent pharmacy filled the following prescriptions for Patient K.J.:

    a. 5/21/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
    b. 7/21/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets
    c. 11/19/18: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets

37. The Respondent pharmacy filled the following prescription for Patient V.E.:

    5/22/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets.

38. The Respondent pharmacy filled the following prescription for Patient T.P.:

    5/22/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets.

39. The Respondent pharmacy filled the following prescription for Patient I.J.:

    5/23/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets.

40. The Respondent pharmacy filled the following prescription for Patient R.S.:

    5/26/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets.

41. The Respondent pharmacy filled the following prescription for Patient R.W.:

    6/01/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets.

42. The Respondent pharmacy filled the following prescription for Patient J.W.:

    5/12/17: Oxycodone-Acetaminophen 10 mg/325 mg, 60 tablets.

43. The Respondent pharmacy filled the following prescription for Patient M.S.:

5/12/17: Oxycodone-Acetaminophen 10 mg/325 mg, 60 tablets.

44. The Respondent pharmacy filled the following prescription for Patient P.F.:

5/22/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets.

45. The Respondent pharmacy filled the following prescription for Patient D.W.:

5/22/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets.

46. The Respondent pharmacy filled the following prescription for Patient K.D.:

5/04/17: Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets.

47. Alprazolam, a type of benzodiazepine, is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(C)(2).

48. Carisoprodol, a type of muscle relaxer, is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(c)(6).

49. Clonazepam, a type of benzodiazepine, is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(c)(11).

50. Diazepam, a type of benzodiazepine, is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(c)(16).

51. Lorazepam, a type of benzodiazepine, is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(c)(30).

52. Methadone is a Schedule II Controlled Substance. *See* 21 CFR § 1308.12(c)(15).

53. Oxycodone is a Schedule II Controlled Substance. *See* 21 CFR § 1308.12(b)(1)(xiii).

54. Phentermine is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(f)(9).

55. Zolipidem, a type of sedative, is a Schedule IV Controlled Substance. *See* 21 CFR § 1308.14(c)(54).

56. Hydrocodone is a Schedule II Controlled Substance. *See* 21 CFR § 1308.12(b)(1)(vi).

57. Dextroamphetamine-Amphetamine, a type of stimulant, is a Schedule II Controlled Substance. *See* 21 CFR § 1308.12.(d)(1).

58. Centreville, MS is 33.2[2] miles from Zachary, LA.

59. Gloster, MS is 41.2 miles from Zachary, LA.

60. Hornbeck, LA is 174.2 miles from Zachary, LA.

61. Independence, LA is 53 miles from Zachary, LA.

62. Liberty, MS is 45.8 miles from Zachary, LA.

63. Vidalia, LA is 80.3 miles from Zachary, LA.

The Government's Case

In addition to the foregoing ponderous number of stipulations, the Government's case consisted of the testimony of a Diversion Investigator and an expert witness.

Diversion Investigator

The first witness to testify was a DEA Diversion Investigator (DI). DI testified that she is currently assigned to the New Orleans Field Division, a position she has held for about two years. Tr. 19. She described her training and responsibilities as a DI, regulating registrants and enforcing Controlled Substances Act (CSA). Tr. 20. In her testimony, DI provided background information about the Louisiana prescription monitoring program (PMP), a database used for the statewide tracking of controlled substance prescriptions. *Id*. DI explained that under Louisiana law, pharmacies doing business in the state are required to enter dispensing data into the PMP for every controlled substance prescription that they dispense. *Id*.

The investigation that culminated in the present administrative charges was initiated by DI2, DI's predecessor. Tr. 21-22. Upon DI2's transfer to DEA Headquarters DI assumed responsibility as the lead DEA investigator on the case and inherited the open and closed evidence requests, as well as the balance of the investigative case file. Tr. 22. According to DI,

[2] The original stipulation reflected the distance between the Respondent pharmacy and Centreville, *Louisiana*. At the Respondent's unopposed request (which was supported by good cause), the stipulation was modified during the hearing. Tr. 149.

the Respondent pharmacy became the focus of DEA's attention based on data acquired during a larger investigation concerning Morris & Dickson, Co., L.L.C (M&D), a major pharmaceutical distributor in Louisiana. Tr. 23. As part of the M&D investigation, it came to DEA's attention that the Respondent pharmacy was one of the top purchasers of oxycodone and hydrocodone in the state. *Id*. DI noted that this was significant because the Respondent was purchasing substantially more oxycodone and hydrocodone than other pharmacies in the area. *Id*. She characterized the Respondent's dispensing as "approximately six or seven times the national average." Tr. 25.

DI testified that during the course of her investigation she reviewed reports from DEA's Automation of Reports and Consolidated Ordering System (ARCOS) database. Tr. 25-26. She explained that DEA registrants are required to input transactions involving controlled substances in Schedules I and II, as well as Schedule III narcotics into ARCOS. *Id.* The information entered by registrants is routinely mined an analyzed by the DEA ARCOS Targeting and Analysis Unit (ARCOS Unit) at DEA Headquarters, which can (as was the case here) generate investigative leads. Tr. 26. DI testified that she reviewed the data forwarded to her by the ARCOS Unit. Tr. 27-28. Through DI, the Government introduced ARCOS data which established some discernible trends regarding the Respondent's purchasing and dispensing of controlled substances. Tr. 33; Gov't. Ex. 71. According to the ARCOS data, in 2015 the Respondent was the sixth highest purchaser of hydrocodone in the state of Louisiana at 677,878 dosage units that year. Tr. 33; Gov't. Ex. 71 at 1-2. In 2016, the Respondent was the second highest purchaser[3], at 677,583 dosage units of hydrocodone. Tr. 33; Gov't. Ex. 71 at 2. This trend of high volume purchasing continued into 2017 where the Respondent was the third highest purchaser at 615,924 dosage units. Tr. 35; Gov't. Ex. 71 at 6.

[3] Throughout her testimony, DI clarified that the data in the ARCOS report refers to the number of dosage units that the Respondent purchased. Tr. 43.

A similar trend was present with respect to the Respondent's purchasing of oxycodone. Tr. 34. In 2015, the Respondent was the fifth highest purchaser of oxycodone, having purchased 519,219 dosage units. Tr. 44; Gov't. Ex. 71 at 7. The Respondent was the seventh highest purchaser in 2016 at 494,730 dosage units. Tr. 34; Gov't. Ex. 71 at 9. In 2017, the Respondent was again the fifth highest purchaser at 482,770 dosage units of oxycodone. Tr. 34-35; Gov't. Ex. 71 at 11-12. According to the averages for 2015 aggregated in the ARCOS report, the pharmacies in the same zip code as the Respondent purchased an average of 174,695 dosage units of oxycodone. Tr. 35; Gov't. Ex. 71 at 15. The state average in 2015 for Louisiana was 102,698 dosage units while the national average was 87,261 dosage units. Tr. 35; Gov't, Ex. 71 at 15.

Within its (70791) zip code in 2015, the Respondent pharmacy was the highest purchaser of hydrocodone. Tr. 36; Gov't. Ex. 71 at 14. The second highest purchaser, a Walgreens, purchased only 191,668 dosage units compared to the Respondent's 677,872. Tr. 36; Gov't. Ex. 71 at 4. The average for its zip code was 202,161 while the state average for Louisiana was 112,588, and the national average was 95,866. Tr. 37; Gov't. Ex. 71 at 16. In 2017, the average purchasing of hydrocodone for pharmacies in the Respondent's zip code was 214,518. Tr. 38; Gov't. Ex. 71 at 19. The state average was 93,636 while the national average was 60,488. Tr. 38; Gov't. Ex. 71 at 19. In 2017, the Respondent was again the highest purchaser of hydrocodone in its zip code. Tr. 39; Gov't. Ex. 71 at 20-21. Medical Pharmacy West (MP West),[4] a pharmacy owned by the same corporate entity as the Respondent, was the second highest purchaser at 182,058 dosage units. Tr. 39; Gov't. Ex. 71 at 21, 40.

In 2015, the average oxycodone purchasing within the Respondent's zip code was 120,274, whereas the Respondent purchased 519,219 dosage units. Tr. 39; Gov't. Ex. 71 at 22. The state average was 55,179 while the national average was 72,729. Tr. 39; Gov't Ex. 71 at 22.

[4] DI testified that MP West and the Respondent pharmacy are "sister pharmacies," sharing common ownership, but she made it clear that only the conduct of the Respondent pharmacy (Medical Pharmacy), was the subject of the present enforcement case. Tr. 40.

Similarly, in 2017, the average purchasing within the Respondent's zip code was 116,706 while the Respondent purchased 482,770 dosage units. Tr. 42; Gov't. Ex. 71 at 28. The state average that year was 53,219 and the national average was 49,415. Tr. 42; Gov't. Ex. 71 at 28.

One peculiar aspect of the Government's table comparisons is the inclusion of a United States Post Office zip code (70072) that did not correspond to the Respondent's registered address or any other location in the universe that bore any logical relationship to the present case.[5] DI had no idea why data regarding 70072 was included, and DI2, who apparently requested the data, was not produced by the Government as a witness. Tr. 153, 172-73. This zip code was used for comparisons on pages 13, 16, 19, 22, 25, and 28 of the ARCOS data report. Tr. 154; Gov't. Ex. 71. In an even stranger development, DI attempted to explain the inclusion of the errant zip code data by inexplicably describing it as an "exemplar" zip code for the state of Louisiana. Tr. 169-70. No one at the hearing seemed to have the foggiest notion as to why information relative to this zip code bore any relation to any relevant fact. In any event, the data pertaining to zip code 70072 was not relevant and was not considered in this recommended decision.

DI stated that purchasing data of this sort indicated that from an investigative standpoint, high purchasing numbers raise the specter that "maybe there's something awry" because a pharmacy purchasing that many dosage units is likely dispensing at a high volume which is an indicator of possible diversion. Tr. 44. She clarified her understanding that it is not against the law to be a high volume purchaser or dispenser, but offered that the data informed their investigation and led the investigators to probe further.[*C] Tr. 44-45. The Louisiana PMP data confirmed that the high volume purchasing was indeed consistent with a concomitantly high

[5] Official notice (upon the concurrence of the parties) was taken that zip code 70072 corresponds to Marrero, Louisiana. Tr. 153-56.

[*C] The information in the DI's testimony related to the volume of controlled substances purchased by Respondent is relevant only to the rationale and foundation for the beginning of DEA's investigation and is considered herein for that purpose alone.

volume dispensing by the Respondent pharmacy.[6] Tr. 45. After reviewing the PMP data and seeing that it corroborated the ARCOS data, DEA acquired the services of an expert, Dr. Diane Ginsburg, to review the data. Tr. 46-47, 72. Prior to requesting the expert report, an administrative subpoena was issued to the Respondent on May 28, 2019. Tr. 47-48; Gov't Ex. 64. This subpoena requested the prescriptions and dispensing data for 30 patients. Tr. 49; Gov't. Ex. 64. Initially not all of the data was provided, but was later supplied in response to an additional subpoena. Tr. 53-54; Gov't. Ex. 66. Another subpoena was issued on September 18, 2019, requesting copies of the prescription fill screens following the dispensing of controlled substances, including pharmacist notations and comments, from January 1, 2017, to March 28, 2019. Tr. 57-58; Gov't. Ex. 66.

Upon review of the responsive material to the first subpoena, the investigators observed that there were no patient profiles or pharmacist comments that corresponded to some of the patients described in the DEA's subpoena. Tr. 53-54. The Respondent was informed that this data was missing and a second administrative subpoena issued. Tr. 53. Additional material was provided in response to the second subpoena.[7] Tr. 53-54. On the issue of compliance with the subpoena, Respondent pharmacy technician TM advised the investigators that where patient profiles and pharmacists' comments were not provided it was because those items do not exist. Tr. 54-56.

---

[6] DI stated that she was given access to the Louisiana PMP, in the form of a username and password, as part of her onboarding process as a diversion investigator. Tr. 178. The witness credibly testified that the application was made through, and granted by, Louisiana state officials, and that Louisiana furnished password-protected access to the data to DI as a DEA investigator. Tr. 177-80. The Respondent initially declined to object to the Government's PMP evidence, but subsequently attempted to interpose an objection after the evidence was accepted in the record. Tr. 130-34. The evidence had been timely supplied by the Government far in advance of the hearing, the Respondent's objection to it was clearly waived, and the evidence was correctly admitted and considered. Tr. 136. However, even in the absence of waiver, the DI's testimony regarding the level of state-controlled access deliberately granted to the DEA investigators by the State of Louisiana sufficiently distinguishes this case from *Grider Drug #1 and Grider Drug #2*, 77 Fed. Reg. 44069, 44071 n.8 (2012), that the evidence is properly considered in these proceedings. Testimony from DI regarding the manner in which her PMP access was granted by the State of Louisiana, coupled with information supplied via email from JF, R.Ph, Assistant Executive Director of the Louisiana Pharmacy Board (Gov't Ex. 76) (no relation to the Respondent pharmacy PIC, Tr. 1064), provides more than a sufficient foundation to admit the PMP evidence as legally procured pursuant to an authorized administrative request under Louisiana law. La. R.S. 40:1007(F)(3).

[7] All of the requested data was received in response to a total for four subpoenas. Tr. 63-64. DI also clarified that the Government's Exhibits 3-63 did not contain all of the copious volume of documents that the Respondent supplied to the DEA in response to the subpoenas, merely a subset of them. Tr. 66-67.

According to DI, upon review of the documents received from the Respondent the investigators concluded that what they saw demonstrated potential evidence of combination prescribing, to include many prescriptions for the "trinity" (an opioid, a benzodiazepine, and carisoprodol) drug cocktail as well as other opioid and benzodiazepine combinations. Tr. 71. Additionally, the materials she reviewed reflected patients who traveled long distances from their home addresses to the Respondent pharmacy, and that many patients received the highest available quantity and strength of various opioids. *Id*.

Based on its evaluation of the data it retrieved from ARCOS, PMP, and the Respondent pharmacy, DEA issued an OSC/ISO. ALJ Ex. 1. DI acknowledged that although under the CSA, an OSC/ISO authorizes the seizure and storage under seal of controlled substances in the possession of the registrant upon whom it is executed,[8] the cognizant DEA officials on the scene declined to seize the drugs and authorized the transfer of the controlled medications to MP West, the Respondent's sister pharmacy. Tr. 162-64. DI allowed that, at least in her view, the decision to allow the transfer of the medications to MP West should not be read as an indication that DEA did not consider the potential charges to be serious. Tr. 164.

DI also conceded that in May of 2016, a period for which ARCOS and PMP data was used to support the issuance of the OSC/ISO, a cyclical investigation[9] of the Respondent was conducted by DEA investigators, and yielded no violations or charges, but she allowed that it was possible that the regulators conducting the cyclical may not have consulted the ARCOS database. Tr. 94, 97-98.

DI presented as an objective regulator/investigator with no discernible motive to fabricate or exaggerate. Indeed, as a successor investigator, she demonstrated commendable candor in teasing out which aspects of her investigation were initiated/controlled by her, and which aspects were inherited. Where she was unsure of an answer (such as the odd inclusion of the ARCOS

[8] 21 U.S.C. 824(f).
[9] The witness testified that cyclical investigations are conducted without advance notice to the registrant. Tr. 94-95.

data relative to the irrelevant zip code), she presented a good-faith effort to analyze the possible basis for generating the information, but made no attempt to supply a convenient contrivance.[10] Viewed in *toto*, the testimony of this witness is sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

Dr. Diane B. Ginsburg

The Government presented the testimony of Dr. Diane Ginsburg, a clinical professor in the Pharmacy Practice Division of the College of Pharmacy at the University of Texas at Austin.[11] Gov't Ex. 2. Her curriculum vitae (CV) reflects myriad teaching and administrative appointments in academia,[12] extensive authorship and publication in pharmacy and educational administration, as well as approximately six years of clinical experience practicing pharmacy in Texas.[13] *Id.* The witness testified that she maintains some level of active involvement with the campus pharmacy at the University of Texas in addition to her prior experience as a retail pharmacist.[14] Tr. 212-14. The witness's CV reflects no actual pharmacy practice or teaching appointments in Louisiana,[15] but she testified that in her view there are no significant differences

[10] This in no way relieves this witness or the Government from the responsibility to actually understand the relevance of the evidence put forth. *Gregg & Son Distributors*, 74 Fed. Reg. 17517, 17517 n.1 (2009) (Agency clarified that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding."). Stated differently, the fact that the Government sponsored evidence under circumstances where no one in the courtroom could intelligibly articulate a reasonable basis for its relevance did not enhance the confidence that can be placed in its witness or its case. This feature is made even more inexplicable by the fact that the initial investigator is currently stationed at DEA Headquarters, less than a mile from the DEA Hearing Facility, and that all testimony in this case was taken by VTC. Still, the irrelevant evidence had no impact, and the wound was not mortal to the Government's case or the witness's credibility.

[11] Dr. Ginsburg testified that she is in her thirty-second year on the University of Texas faculty. Tr. 207.

[12] The witness testified that she currently teaches courses in pharmacy law, inter-professional ethics, and foundations of professional development. Tr. 214.

[13] Dr. Ginsburg testified that she has been licensed to practice pharmacy in Texas since 1984. Tr. 209.

[14] Dr. Ginsburg testified that although she has filled in sporadically (but not recently) as a line pharmacist at the campus pharmacy (Tr. 213-14, 246-48), she is not the pharmacist-in-charge (PIC) (Tr. 213), and her name does not appear on the campus pharmacy license. Tr. 243-46.

[15] Gov't Ex. 2. Past Agency precedent has not required that expert witnesses maintain licensure in the state(s) where their professional expertise is elicited. *See, e.g., Wesley Pope, M.D.*, 82 Fed. Reg. 14,944, 14,976 (2017) (holding that testimony of the Government's expert witness merited controlling weight notwithstanding lack of applicable state licensure or experience. [omitted]. In fact, the Agency has even held that there is no requirement that an expert witness be licensed in any state at all. *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7324 n.48 (2018). [However, as is the case here, expert witnesses from out of state generally demonstrate an understanding of the applicable standard of care and usual course of professional practice and the foundation for this understanding. In this case, the expert witness's testimony was supported by Louisiana law.]

between the pharmacy standards applicable in Texas versus in Louisiana.[16] Tr. 215. Dr. Ginsburg was offered[17] by the Government and accepted as an expert in the field of pharmacy practice, and specifically pharmacy practice in Louisiana.[18] Tr. 271.

Dr. Ginsburg testified that the applicable standard of care requires that before dispensing a controlled substance, a pharmacist must engage in a defined protocol to ascertain whether the medicine was prescribed for a legitimate medical purpose. Tr. 273. Specifically, in Dr. Ginsburg's opinion, the dispensing pharmacist must perform the following steps prior to dispensing: (1) verify the prescriber's licensure and DEA registration status;[19] (2) verify that the dose is correct; (3) verify that the drug is correct; (4) verify that the patient directions are correct; (5) consult with the state PMP to check for pharmacy and/or doctor shopping. Tr. 273-74. Additionally, Dr. Ginsburg testified that there are multiple "holistic"[20] considerations that a

---

[16] Dr. Ginsburg testified that during her academic tenure she has had the opportunity to compare Louisiana and Texas pharmacy practice standards. Tr. 216.

[17] Tr. 219.

[18] At the hearing and in its post-hearing brief, the Respondent objected to the classification of Dr. Ginsburg as an expert. Tr. 269-70; ALJ Ex. 20 at 8-10. The Respondent's objection at the hearing was noted on the record and Dr. Ginsburg's expert testimony was admitted over that objection. Tr. 271. [Respondent again objected in his Exceptions and argued, in the alternative, that her "lack of qualifications should have been taken into account in determining what weight to give her opinions." Resp Exceptions, at 1. Repeating the arguments Respondent made before the Chief ALJ, Respondent took exception to Dr. Ginsburg's lack of recent work experience in retail pharmacy, her lack of research work and publications, her lack of prior testimony regarding "red flags," and, amongst other things, her lack of any practice or license in Louisiana. *Id.* at 1-5. Respondent also again pointed out that Dr. Ginsburg rendered her opinion that Medical Pharmacy was improperly filling prescriptions for controlled substances that had one or more red flags without first having the pharmacy records from which she could determine whether or not the red flags had been resolved. *Id.* at 3-4. All of these issues were considered by the Chief ALJ both during the hearing and in the RD and I agree with the ALJ's determination. I find that Dr. Ginsburg was a credible witness. I find that Dr. Ginsburg primarily relied on Louisiana law and regulations to formulate her opinion regarding the usual course of professional practice and a pharmacist's corresponding responsibility and the laws provide extremely strong support for her testimony. *See infra* The Analysis. For example, Dr. Ginsburg testified that Louisiana requires pharmacists to exercise their corresponding responsibility, Tr. 275, and indeed, Louisiana states that "[t]he responsibility for the proper prescribing of controlled substances rests upon the prescribing practitioner; however, a corresponding responsibility rests with the pharmacist who dispenses the prescription." La. Admin Code tit. 46, Part LIII, § 2745(b)(1). Also, Dr. Ginsburg testified that to ensure a prescription is issued for a legitimate medical purpose, "[y]ou would look at some of the things that would, I guess, raise the red flag, although that is not an official legal term. . . . [Y]ou would look at quantity, . . . other medications being prescribed, . . . duration of therapy . . . [you would] look also holistically in terms of within that patient profile. Those are examples of a few things." Tr. 275-76. This is supported by La. Admin Code tit. 46, Part LIII, § 515 which says "[a] pharmacist shall review the patient record and each prescription presented for dispensing for purposes of enhancing pharmacy care and therapeutic outcomes by recognizing the following potential situations: 1. Drug over-utilization or under-utilization; 2. Therapeutic duplication; . . . 4. Drug-drug interactions; 5. inappropriate drug dosage or treatment duration; 6. drug-allergy interactions; 7. or clinical abuse/misuse." Moreover, it appears that the expert opinions generally relied upon in this decision were largely uncontested.]

[19] [Omitted for relevance.]

[20] At another point in her testimony, the witness testified that checking the patient profile maintained by a pharmacy is encompassed within her definition of a "holistic" analysis. Tr. 282-83.

pharmacist must factor into the mix, such as the quantity of medication being prescribed, other medications that may have been simultaneously prescribed, and the duration of the therapy. Tr. 275-76. In Dr. Ginsberg's opinion, it is incumbent upon the dispensing pharmacist to contact the prescriber to resolve any issues raised regarding any of the foregoing wickets, or even the state medical board or law enforcement in some cases. Tr. 273-74, 276. According to Dr. Ginsburg, documentation memorializing the resolution of any conflict constitutes a minimum standard of conduct.[21] Tr. 280. Dr. Ginsburg also discussed a pharmacist's corresponding responsibility to ensure that a controlled substance prescription is issued for a legitimate medical purpose. Tr. 274-75.

Although not included in the defined protocol that she outlined early in her testimony, Dr. Ginsburg outlined various features, or "red flags," that must (presumably in the manner of the other listed potential anomalies in her described protocol) be resolved prior to controlled substance dispensing. Tr. 275-76. Dr. Ginsburg testified that because pharmacists comprise a type of safety net, all encountered red flags of diversion must be identified, resolved, and documented prior to any controlled substance being dispensed. Tr. 711. In Dr. Ginsburg's view, a pharmacy falls short of the applicable standard of care where red flags are not addressed and documented prior to dispensing, irrespective of the legitimacy of the prescription.[22] Tr. 712-14. Specifically, she discussed a phenomenon described as a "prescription cocktail" or a "trinity" combination. Tr. 284-87. According to Dr. Ginsburg, a trinity or cocktail is defined by the simultaneous prescribing of an opioid in combination with a benzodiazepine and a muscle relaxant. Tr. 287. This combination presents a heightened risk of respiratory and/or central nervous system depression, but is sought after by drug abusers for the gratuitous euphoric effect it produces.[23] Tr. 286, 379-80.

---

[21] The memorialization could be affixed to the back of a prescription by handwritten note or entered electronically into a pharmacy database. Tr. 281.

[22] [Omitted for relevance.]

[23] The dangers of cocktail prescribing are outlined in a guidance document issued by the Food and Drug Administration (FDA Guidance Document), which was received in the record. Gov't Ex. 67; Tr. 289. The FDA

Dr. Ginsburg testified that although dispensing events[24] CH1-CH4,[25] JMB1-JMB4,[26] JMB6-JMB8,[27] JMB9-JMB13,[28] JMB16-JMB19,[29] JMB20-JMB22,[30] JMB24-JMB26,[31] JMB30-36,[32] JMB40-JMB43,[33] JMB49-JMB51,[34] TD1-TD4,[35] DG1-DG6,[36] DG7-DG-9,[37] DG7-DG14,[38] DG18-DG20,[39] DG24-DG30,[40] DG33-DG35,[41] DG45-DG56,[42] JH1-JH26,[43] RI1-RI5,[44] RI19-RI25,[45] JB2-JB3,[46] PW1-PW6,[47] LH1-LH3,[48] AP1-AP2,[49] MA1-MA3,[50] BB1-BB11,[51] TD1-TD2,[52] LD1-LD3,[53] and RW1-RW4[54] demonstrated evidence of prescription trinity cocktails, there was no evidence in the electronic data provided by the Respondent that this red flag was

---

Guidance Document included the dangers of cocktail prescribing as a "black box warning," the most serious variety of warning issued by that agency. Gov't Ex. 67 at 1; Tr. 290. Dr. Ginsburg testified that a practicing pharmacist is responsible for familiarity with the existence and content of the FDA Guidance Document, including the details and nature of the black box warning. Tr. 289. However, Dr. Ginsburg acknowledged that FDA did not attempt to announce a prohibition on prescribing this combination of medications under all circumstances or classify the combination as *per se* illegitimate. Tr. 582-83. Dr. Ginsburg agreed that under some circumstances, such as in end-of-life or palliative care scenarios, the combination could be appropriate. Tr. 591.

[24] Dispensing events such as those pertaining to specific patients, are the subject of stipulation by the parties and are set forth in a table in the Appendix to this recommended decision.

[25] Tr. 306-08; Gov't Ex. 3. Dr. Ginsburg testified that an additional opioid was also present. Tr. 307.

[26] Tr. 309-13. Dr. Ginsburg testified that she noted two opioids, a skeletal muscle relaxant, and a benzodiazepine. Tr. 311.

[27] Tr. 313-14. Dr. Ginsburg testified that she also identified an additional opioid. Tr. 314.

[28] Tr. 314-16.

[29] Tr. 316-17.

[30] Tr. 317-18

[31] Tr. 318-19.

[32] Tr. 319-20.

[33] Tr. 320-21.

[34] Tr. 321-22. Dr. Ginsburg testified that JMB49 and JMB50 are examples of drug combinations that are the subject of the FDA black box warning. Tr. 367-72; Gov't Ex. 67. She further explained that an FDA black box warning creates a red flag that requires resolution prior to dispensing. Tr. 371-72.

[35] Tr. 322-27.

[36] Tr. 327-30.

[37] Tr. 330-31.

[38] Tr. 331-32.

[39] Tr. 332-34.

[40] Tr. 335-37.

[41] Tr. 338-39.

[42] Tr. 340-43.

[43] Tr. 343-51; Gov't Ex. 15.

[44] Tr. 352-363; Gov't Ex. 18.

[45] Tr. 363-65.

[46] Tr. 374-75; Gov't Ex. 19.

[47] Tr. 375-78; Gov't Ex. 20.

[48] Tr. 379-81; Gov't Ex. 21.

[49] Tr. 381-83; Gov't Ex. 22.

[50] Tr. 383-84; Gov't Ex. 23.

[51] Tr. 385-88; Gov't Ex. 24. Dr. Ginsburg further testified that the disparity in strength among the prescribed benzodiazepines raised another variety of red flag that required (and did not receive) documented resolution prior to dispensing by the Respondent. Tr. 389-90.

[52] Tr. 390-93; Gov't Ex. 7.

[53] Tr. 393-94; Gov't Ex. 27.

[54] Tr. 394-96; Gov't Ex. 28.

the subject of resolution or inquiry by pharmacists or pharmacy staff with respect to these patients. Tr. 714-15. Dr. Ginsburg rendered her expert opinion (not contradicted on this record) that these prescriptions were not issued for a legitimate medical purpose in the usual course of a professional practice in Louisiana. Tr. 308, 312, 314, 316-20, 322, 325, 330, 336-43, 347-51, 358, 359-66, 376-88, 392-93, 395-96, 550-52.

The second red flag described by Dr. Ginsburg is "pattern prescribing." Tr. 290-91. She described pattern prescribing as a combination of certain medications in the same strength, combination, and/or quantity, with sufficient regularity to cause a reasonable pharmacist to "question whether there is [an] individual patient-physician relationship and [whether] those medications [are] being prescribed for a legitimate purpose." Tr. 291-94; *see also, id*. at 434-35, 648-51. Dr. Ginsburg testified that this variety of red flag is potentially resolvable by consulting with the prescriber and documenting that resolution. Tr. 294-95.

Dr. Ginsburg testified that although dispensing events TD1-TD7,[55] DG7-DG9,[56] DG12-DG14,[57] DG15-DG23,[58] DG27-DG30,[59] and DG45-DG56[60] demonstrated clear evidence of pattern prescribing, the records procured from the Respondent pharmacy revealed no identification or resolution of this red flag by pharmacists or pharmacy staff. Tr. 714. Dr. Ginsburg rendered her expert opinion that these prescriptions were not issued for a legitimate medical purpose in the usual course of a professional practice in Louisiana. Tr. 327, 329-31, 336-37, 550-52.

According to Dr. Ginsburg, a subset of pattern prescribing arises when presented scrips show repeated prescriptions by the same prescriber for the highest allowable strength and quantity of a controlled substance (quantity and strength pattern prescribing). Tr. 302-03, 434-35, 600-01, 610. This is so, in her view, because medications such as opioids are started at "as

---

[55] Tr. 322-27; Gov't Ex. 8.
[56] Tr. 330-31.
[57] Tr. 331-32.
[58] Tr. 332-35.
[59] Tr. 335-37.
[60] Tr. 340-43.

low a dose as possible." Tr. 303. In her testimony, Dr. Ginsburg described this variety of pattern prescribing this way:

> Pattern prescribing is prescribing [the] same medications for multiple patients [with n]o deviation in terms of quantity, highest strength, usually the same agents over and over for multiple people.

Tr. 473. Regarding this subset of pattern prescribing, Dr. Ginsburg explained that:

> [W]hen you start seeing prescription after prescription, after prescription, from the same prescriber, and they're all the same for the highest strength, and you know, a very, very large quantity, and the quantity is consistent, that . . . speaks to it not being individualized for a patient . . . [a]nd . . . potentially not being legitimate.

Tr. 303. Dr. Ginsburg testified that this red flag is identifiable by consulting with the state PMP and characterized this red flag as potentially resolvable by contacting the prescriber. Tr. 304.

Dr. Ginsburg testified that although the Respondent had clear evidence of quantity and strength pattern prescribing, the records procured from the Respondent revealed no identification or resolution of the issue. Tr. 714. Specifically, she identified quantity and strength pattern prescribing relative to prescriptions filled that were issued by a local prescriber, Dr. GB. Tr. 435; Gov't Ex. 4 at 1. She identified pattern prescribing by Dr. GB relative to dispensing events JMB41[61], JMB43[62], JMB44[63], JMB46[64], JMB50,[65] PB2,[66] BE1,[67] TP1,[68] IJ1,[69] RS1,[70] RW1,[71] as well as multiple other dispensing events[72] that were not subject to stipulation, and thus, not contained in the Appendix.[73] The Government's expert also identified numerous quantity and strength pattern prescribing events relative to prescriptions that were issued by AH, a local nurse

---

[61] Tr. 475-76; Gov't Ex. 4
[62] Tr. 476-77.
[63] Tr. 477.
[64] Tr. 477-78
[65] Tr. 478-479; Gov't Ex. 4 at 1.
[66] Tr. 479-80; Gov't Ex. 35 at 1.
[67] Tr. 481-82; Gov't Ex. 50 at 23.
[68] Tr. 493-94; Gov't Ex. 51 at 5.
[69] Tr. 494-95; Gov't Ex. 52 at 7.
[70] Tr. 495-96; Gov't Ex. 55 at 1.
[71] Tr. 498-500; Gov't Ex. 28 at 2.
[72] Tr. 482-84, 493-94, 496-97; Gov't Ex. 50 at 1.
[73] This feature about the Government's case was less than helpful.

practitioner.[74] Tr. 502. In Dr. Ginsburg's opinion, dispensing events JB3[75] and DL2[76] involving AH-issued controlled-substance prescriptions demonstrated quantity and strength pattern prescribing indicia that were not resolved in the documentation supplied by the Respondent. Tr. 714. Likewise, she identified the following dispensing events on prescriptions issued by Dr. AP as reflecting the same red flag: CS1,[77] CS2,[78] PR1,[79] PR2,[80] and other un-stipulated dispensing events.[81] Dispensing events effected in the face of unresolved quantity and strength pattern prescribing red flags related to prescriptions issued by Dr. MM were also identified. Tr. 516. The following dispensing events on Dr. MM prescriptions were highlighted by Dr. Ginsburg: BB2,[82] KC1,[83] GC1,[84] VM1,[85] KD1,[86] as well as other un-stipulated dispensing events related to this doctor.[87] Additional dispensing events effected in the face of unresolved quantity and strength pattern prescribing red flags related to prescriptions issued by Dr. BJ were also identified. Tr. 527. The following dispensing events on Dr. BJ prescriptions were testified to by Dr. Ginsburg: JW1,[88] MS1,[89] PF1,[90] DW1,[91] and other non-stipulated dispensing events as well.[92] Dr. Ginsburg rendered her expert opinion (not contradicted on this record), informed further by her research based on the individual specialties of the respective prescribers,[93] that

---

[74] Tr. 779.
[75] Tr. 503-04; Gov't Ex. 19 at 14.
[76] Tr. 504-05; Gov't Ex. 40 at 1.
[77] Tr. 506-08; Gov't Ex. 37 at 1.
[78] Tr. 508; Gov't Ex. 37 at 1.
[79] Tr. 508-09; Gov't Ex. 39 at 1.
[80] Tr. 508-09; Gov't Ex. 39 at 1.
[81] Tr. 509-11; Gov't Ex. 39 at 1. *See* footnote 74.
[82] Tr. 516-17; Gov't Ex. 24 at 3.
[83] Tr. 519-20; Gov't Ex. 42 at 20.
[84] Tr. 521-22; Gov't Ex. 43 at 2.
[85] Tr. 522-23; Gov't Ex. 44 at 1.
[86] Tr. 524-26; Gov't Ex. 60 at 1.
[87] Tr. 519-22; Gov't Exs. 42 at1, 43 at 2. *See* footnote 74.
[88] Tr. 527-28; Gov't Ex. 56 at 3.
[89] Tr. 529-30; Gov't Ex. 57 at 2.
[90] Tr. 531-32; Gov't Ex. 58 at 1.
[91] Tr. 533-34; Gov't Ex. 59 at 1.
[92] Tr. 528-35; Gov't Exs. 56 at 1, 57 at 2, 58 at 1, 59 at 1. *See* footnote 74.
[93] Tr. 594. Curiously, although the witness testified that she researched and factored in the practice areas of the prescribers into her pattern-prescribing conclusions, she conceded that she declined to include this analysis point in any of the prior reports she supplied to DEA during the run up to the hearing. Tr. 638-39. That said, Dr. Ginsburg gave credible and persuasive testimony that the practice areas of the prescribers did properly form part of the basis for the opinions she rendered during her testimony. Tr. 594, 639-41.

these prescriptions were not issued for a legitimate medical purpose in the usual course of a professional practice in Louisiana, and that none of the documented resolutions required to meet the minimal standard of care in Louisiana were evident in the paperwork supplied by the Respondent. Tr. 502-03, 505-06, 512-16, 526, 535-38, 550-52.

The third red flag presented by Dr. Ginsburg is distance prescribing, or controlled substance prescriptions presented to pharmacists by customers travelling a long distance to obtain prescriptions and get them filled at a specific pharmacy. Tr. 295. She described it as illogical that a customer, for no valid reason, would travel a significant distance to pick up a prescription at a particular pharmacy where others are closer. Tr. 296. According to Dr. Ginsburg, distance prescribing suggests that the customer is traveling to a particular "pharmacy that would not question large quantities or large doses of certain prescriptions." Tr. 538. Like pattern prescribing, distance prescribing is a red flag that is amenable to resolution by contacting the prescriber and documenting the outcome. Tr. 295-97. Dr. Ginsburg testified that the distance information is generally procured upon customer intake and generally available on the pharmacy's patient profile. Tr. 296.

Dr. Ginsburg identified dispensing events PR1-PR2 (41.2 miles),[94] TB1-TB4 (174.2 miles),[95] KR1-KR2 (53 miles),[96] LW1-LW4 (45.8 miles),[97] and KJ1-KJ3 (80.3 miles)[98] as indicating distance prescribing red flags that were not the subject of documented resolutions by the pharmacists or staff at the Respondent pharmacy. Tr. 714. Dr. Ginsburg rendered her expert opinion that based on the unresolved distance red flags present, these prescriptions were not issued for a legitimate medical purpose in the usual course of a professional practice in Louisiana, and none of the documented resolutions required to meet the minimal standard of care in Louisiana were evident in the paperwork supplied by the Respondent. Tr. 549-52.

---

[94] Tr. 539-41; Gov't Ex. 39.
[95] Tr. 541-43; Gov't Ex. 46.
[96] Tr. 543-45; Gov't Ex. 47.
[97] Tr. 545-47; Gov't Ex. 48.
[98] Tr. 547-49; Gov't Ex. 49.

A fourth red flag outlined by Dr. Ginsburg is alternating methods of payment. Tr. 297. This red flag, according to Dr. Ginsburg, is present when a customer utilizes multiple payment methods to procure different medications, including but not limited to cash, private insurance, Medicaid or Medicare. Tr. 297-98, 398-99. Dr. Ginsburg opined that alternating methods of payment can be an indicator that a pharmacy customer is attempting to shield particular medication purchases, such as opioids, from insurance companies who may be on the lookout for diversion red flags, such as duplicative therapies and/or problematic medication combinations. Tr. 298-99. It is Dr. Ginsburg's view that the standard of care requires a dispensing pharmacist to identify, resolve, and document this type of diversion red flag, which can be accomplished by either consulting with the prescriber, a discussion with the customer, and/or analyzing the pharmacy patient profile. Tr. 302-03, 401-02, 415-16. According to Dr. Ginsburg, benign explanations for alternative methods of payment should be explained by pharmacy staff in the comment section of the pharmacy's software and there was no evidence of such documentation in the pharmacy records. Tr. 667-68, 714-15.

Dr. Ginsburg identified alternating methods of payment red flags regarding customers JMB,[99] DM,[100] KS,[101] and TD[102] but no indication that this red flag was identified or resolved by any pharmacist of pharmacy staff in any of the documentation procured from the Respondent. Dr. Ginsburg rendered her expert opinion that these prescriptions were not issued for a legitimate medical purpose in the usual course of a professional practice in Louisiana. Tr. 423-26, 434, 550-52.

Notwithstanding brief, inconsequential, passing flashes of mild defensiveness exhibited during cross-examination, Dr. Ginsburg presented as an authoritative, careful, persuasive expert witness who provided her opinions dispassionately and without overt evidence of agenda.

---

[99] Tr. 411-19, 422-24; Gov't Exs. 4, 68A at 3, 70A at 1.
[100] Tr. 424-26; Gov't Exs. 34, 68A at 34. Dr. Ginsburg also testified that in her opinion, there was evidence of duplication of therapy that was not addressed by the Respondent pharmacy prior to dispensing. Tr. 425-26.
[101] Tr. 427-29; Gov't Ex. 68A at 41.
[102] Tr. 429-34; Gov't Exs. 7, 8, 68A at 13.

Additionally, Dr. Ginsburg's expert testimony stands largely uncontroverted, and for the most part unchallenged in any persuasive way on this record, and will be afforded controlling weight.

The Respondent's Case

Daren L. Vicellio

Daren Vicellio is and has been the General Manager of both Medical Pharmacy and Medical Pharmacy West (MP West) since 2011. Tr. 800. He testified that he is not a pharmacist,[103] but he is the son-in-law of Audrey LeTard, the current owner of Medical Pharmacy, Incorporated (MP, Inc.), the corporate entity which owns both pharmacies. Tr. 799, 803. Mr. Vicellio testified that (like his father-in-law[104]) he grew up in Zachary, Louisiana and attended Louisiana State University where he majored in Industrial Technology Safety. Tr. 801-02.

According to Mr. Vicellio, Zachary, Louisiana, where both the Respondent pharmacy and MP West are located, is a town of 17,000 to 18,000 people that lies about twenty miles north of Baton Rouge. Tr. 802. The Respondent pharmacy was established in 1968 by his late[105] father-in-law John LeTard, a pharmacist. Tr. 802, 805. Mr. Vicellio related that Mr. LeTard had a long, distinguished career as a pharmacist, first working for his own step-father (also a pharmacist) before opening his own pharmacy (the Respondent pharmacy) that has been doing business in the same location in Zachary since 1968. Tr. 803, 807-08. The late Mr. LeTard's accomplishments include a gubernatorial appointment to the Louisiana Board of Pharmacy (Louisiana Pharmacy Board or the Board) in 2008, serving as a board member at Lane Memorial Hospital for over two decades (nineteen as the hospital board's chairman), and a prestigious award from the American Pharmacists Association. Tr. 808, 839. Mr. Vicellio's testimony credibly depicts the late Mr. LeTard as a pillar of the local community, and the pride he

[103] Mr. Vicellio testified that he held various positions with the United Parcel Service (UPS) and a hunting retreat called Bush Hill Plantation. Tr. 804. Bush Hill Plantation, like the Respondent pharmacy, was owned by the late Mr. LeTard. Tr. 805-06.
[104] Tr. 807.
[105] Mr. Vicellio testified that his father-in-law, Mr. LeTard, passed away from cancer in 2016. Tr. 802-03.

conveyed at the hearing about his late father-in-law's accomplishments was palpable and genuine.

Mr. Vicellio provided much helpful background regarding the history of the Respondent pharmacy and MP, Inc. The two pharmacies operated by MP, Inc. collectively employ eight pharmacists, eight pharmacy technicians, six clerks, three office personnel, and two drivers. Tr. 842. Both pharmacies offer free delivery of prescriptions,[106] and a loyalty program for regular customers, which, according to the witness, is frequently used when a customer's insurance will not cover certain prescriptions. Tr. 845. Mr. Vicellio stated that there are several other pharmacies in Zachary: Walmart, Walgreens, CVS, and another independent pharmacy, Dry's Pharmacy. Tr. 808-09. He further stated that the Respondent pharmacy has always been the largest pharmacy in Zachary, "more than double anybody else in town." Tr. 810. Within the time period of the ISO, October 2016 through October 2019, the Respondent pharmacy filled 798,255 prescriptions for 22,629 patients. Tr. 810-12. Mr. Vicellio stated that prior to the OSC/ISO, the Respondent pharmacy was "very successful" with a "great reputation, not only in Zachary, but in the whole state of Louisiana." Tr. 814. He further stated that DEA has taken no action against the COR maintained by MP West, and that the Respondent pharmacy is still open for business; just not presently filling prescriptions for controlled substances. Tr. 814-15.

Mr. Vicellio recounted that when he first began work for Mr. LeTard at the Respondent pharmacy, he primarily handled scheduling and maintenance. Tr. 806. He took on a more prominent role in 2010 when his father-in-law was diagnosed with cancer. Tr. 806-07. As Mr. Vicellio explained, Mr. LeTard "didn't know how the cancer was going to go and he wanted somebody that would be in place that he trusted and would take care of everything for him." Tr. 807. Mr. Vicellio testified that the Respondent pharmacy has a very large and loyal customer base and that they "come from miles away because of the relationship we have with these customers." Tr. 815. After the OSC/ISO, The Respondent pharmacy has referred customers to

[106] Tr. 842.

MP West to fill controlled substance prescriptions but Mr. Vicellio explained that MP West "is on the other side of town and a lot of the patients are coming from the other side that we're on and some of them do not want to go down there because there's too much of an inconvenience." Tr. 815-16. This has led to the Respondent pharmacy losing some customers. Tr. 816. By Mr. Vicellio's estimation, the level of business at the Respondent pharmacy has gone down from 900 prescriptions per day to about 600 prescriptions per day. *Id*. He further testified that at the time the OSC/ISO was served, controlled substance dispensing constituted about fifteen percent of the prescriptions filled at the Respondent pharmacy. Tr. 817. Mr. Vicellio also represented that the Respondent pharmacy was not making significant profits from improperly filled controlled substances.[107] Tr. 844. As a result of the OSC/ISO, the percentage of controlled substance prescriptions filled at MP West has gone up. Tr. 818. Mr. Vicellio testified that the DEA has been informed of this development to account for the upswing in that pharmacy's controlled substance traffic. *Id*. The Respondent pharmacy has also posted a notification in their store informing customers that it is currently unable to fill controlled substance prescriptions. Tr. 819. He describes the OSC/ISO as a "black eye in the community" of pharmacists and pharmacies.[108] *Id*.

Mr. Vicellio testified that as a result of the OSC/ISO, the MP, Inc. pharmacies no longer fill controlled substance prescriptions issued by Dr. GB, a physician whom Dr. Ginsburg identified during her testimony as a pattern prescriber. Tr. 820, 861. The Respondent pharmacy also lost one of its wholesalers following the OSC/ISO. Tr. 821-23. According to Mr. Vicellio, because this wholesaler was no longer able to claim rebates from manufacturers without the

---

[107] According to Mr. Vicellio, the market is locally competitive, with only a modest profit margin on drugs. Tr. 844.

[108] Mr. Vicellio further related how painful it was to inform his mother-in-law, Mrs. LeTard, the owner of MP, Inc., of the OSC/ISO and its consequences. Tr. 834. According to Mr. Vicellio, his father-in-law "brought [him] into the [Respondent pharmacy] to be the manager when he was gone and to also make sure the [Mrs. LeTard] was taken care of." Tr. 833-34. Mr. Vicello explained his relationship with Mrs. LeTard this way: "[B]asically, she is the owner. I am the general manager and I run both [MP, Inc. pharmacies]. I report to her. But my job is to let her enjoy life and not be worried about these [pharmacies] and that's what my goal is to achieve here, and make sure we get everything up and running correctly and do it the right way." Tr. 834. Mr. Vicellio testified that he feels that he "let [his mother-in-law] down by getting this ISO." Tr. 854.

Respondent pharmacy maintaining an active COR, it sought to pass the added costs onto the Respondent pharmacy.[109] Tr. 822-23. Mr. Vicellio also related that Morris & Dickson, a drug distributor, also will no longer sell controlled substances to MP West because of the OSC/ISO affecting the Respondent pharmacy. Tr. 823.

Mr. Vicellio testified that when the first two administrative subpoenas from DEA arrived, his sense was that prescribers, not the Respondent pharmacy, were the focus of the investigation. Tr. 825. When asked to supply data from the comment fields in response to one of the administrative subpoenas, Mr. Vicellio testified that not all of the requested information was provided because "[i]t was probably nothing to supply. There were no comments." Tr. 862. It was Mr. Vicellio's position that blank comment sections were not supplied because of the difficulty in retrieving that information from legacy software that had been replaced. Tr. 864-65. He explained that the pharmacy "[has] all the prescription records like we're supposed to" but in order to print the comment sections "we had to go back into the old software, which we don't really have a license for anymore." *Id*. DEA personnel who served the OSC/ISO seized paper documents but the pharmacy computers were not imaged.[110] Tr. 865.

During his testimony, Mr. Vicellio (a non-pharmacist) admitted that he did not know what a diversion red flag was until the OSC/ISO was served. Tr. 832-33. He stated that he is now aware that the trinity cocktail prescriptions posed potential harm to the patients taking them. Tr. 825-26. Although the Respondent pharmacy was presumably manned by qualified pharmacists and staff, its manager, Mr. Vicellio, testified that the first inkling that the organization had anything amiss was upon the service of the OSC/ISO that forms the basis of this case. *Id*.

[109] Mr. Vicellio testified that this added cost applied to controlled and non-controlled drugs. Tr. 820-22.
[110] Interestingly, although the CSA authorizes the seizure of all controlled substances upon the service of an OSC/ISO, 21 U.S.C. § 842(f), Mr. Vicellio testified that the DEA personnel on scene did not confiscate the controlled substances on hand at the Respondent pharmacy, but instead permitted the drugs to be transferred to MP West. Tr. 828-29. This was an act of lenity for which Mr. Vicellio acknowledged he was "very thankful." Tr. 829.

Mr. Vicellio testified that upon studying the OSC/ISO, he understood that the Respondent pharmacy was, as he put it, "deficient in some areas," and he began formulating a strategy to help ensure compliance in the future. Tr. 830. Written policies and procedures for both pharmacies were (for the first time)[111] developed. *Id*. Interestingly, Mr. Vicellio testified that prior to the written policies generated by MP, Inc. after the OSC/ISO, "[i]t was for the pharmacists—each pharmacist's professional judgment to make the call on prescriptions."[112] Tr. 833. James Bryce (the Respondent's other witness in this case), the MP West pharmacist in charge (PIC), was designated as the newly-created compliance officer for both MP, Inc. pharmacies. Tr. 830. Mr. Vicellio testified that Mr. Bryce was selected for this role because he is "the most knowledgeable" of their pharmacists and "a stickler for rules." Tr. 831. On December 22, 2019, a mandatory training session[113] was conducted for the employees of both MP, Inc. pharmacies (although only MP West is currently authorized to handle controlled substances) about new policies and procedures where the staff was informed that "if somebody doesn't do it the right way they are not going to be employed with us." Tr. 832, 850. Mr. Vicellio testified that the policies and procedures recently adopted at MP West to handle the filling of controlled substance prescriptions are ready to be implemented at the Respondent pharmacy if its COR is reinstated.[114] Tr. 848. All of the pharmacists at both locations have learned these new protocols and worked at MP West during the implementation phase. Tr. 848. Inasmuch as no new staff members have been added since the mandatory training, all MP, Inc. pharmacists and pharmacy technicians have had this training. Resp't Ex. 2; Tr. 850.

---

[111] Mr. Vicellio stated that prior to the OSC/ISO there were no established procedures for identifying and resolving red flags. Tr. 833. He acknowledged that prior to the OSC/ISO, neither of the MP, Inc. pharmacies had written policies and "that's on [him]." Tr. 837. The Respondent pharmacy did not have written policies because Mr. LeTard did not have written policies and Mr. Vicellio did not previously appreciate their necessity. Tr. 838.

[112] A disorganized document, which purports to be filled with controlled substance scrips that had been presented to and rejected by pharmacists and staff at the Respondent pharmacy, and which was titled "Medical Pharmacy's Due Diligence File – Pre-ISO," was received into the record. Resp't Ex. 3; Tr. 857-58.

[113] An attendance roster of MP, Inc. employees who attended the training session was received into the record. Resp't Ex. 2; Tr. 849-51.

[114] A 16-page controlled substance policy document for the MP, Inc. pharmacies was received into the record. Resp't Ex. 1; Tr. 847-49.

Mr. Vicellio acknowledged that he understands that the CSA and its associated regulations did not suddenly materialize in 2019 and that operating a pharmacy is a highly-regulated activity. Tr. 834-35. He is likewise aware that pharmacists, as practitioners in this area, have legal obligations that must be followed for them to engage in this highly regulated activity. Tr. 835. Mr. Vicellio theorized that one problem may have been that the previous practice of the staff at the MP, Inc. pharmacies was to stay current by exclusively reviewing publications from the Louisiana Pharmacy Board, which (apparently to his knowledge) did not contain references to cocktail prescribing or diversion red flags. Tr. 835, 840. Mr. Vicellio, somewhat incongruently, acknowledged that the pharmacists he employs bear a responsibility to follow not only Louisiana state law, but also the CSA, its ensuing regulations, and rulings by the DEA Administrator. Tr. 866. Needless to say, shifting the blame for non-compliant pharmacists and staff to the supposed quality of materials available from the Louisiana Pharmacy Board did not serve to enhance the Respondent's presentation in this regard.[115] From his perspective, as a non-pharmacist, Mr. Vicellio testified that he assumed that the pharmacists he hired were properly trained and would ensure the business's compliance with applicable laws. Tr. 836. However, even in the face of Mr. Vicellio's acknowledgement that the pharmacists and staff he employed at the Respondent pharmacy were clearly delinquent in following unequivocal federal, state, and professional standards, not a single pharmacist or employee from the Respondent pharmacy has been fired or disciplined. Tr. 836-37. The past notwithstanding, Mr. Vicellio testified that he has confidence in his employees and expects that they will (now) comply with the new policies and procedures. Tr. 843.

As the general manager of both MP, Inc. pharmacies, Mr. Vicellio is inherently and inescapably imbued with the greatest motive attached to the outcome of the case. While his position, standing alone, is not fatal to his credibility, it certainly must be factored into the

[115] At the behest of his counsel, Mr. Vicellio conceded that the absence of these references does not constitute a defense to the charges. Tr. 841.

equation. Further, this witness acknowledged that he feels personally responsible for the Respondent pharmacy's transgressions, and that he let down his mother-in-law by running a pharmacy that was closed down by an ISO. Tr. 833-34. Objectively, the motivations to minimize culpability and maximize the scope of remedial steps and acceptance of responsibility (all of which he arguably did) are certainly present. As discussed, *supra*, Mr. Vicellio's subtle attempt to shift the responsibility for substandard dispensing to reliance on his subordinate pharmacists and staff, as well as perceived deficiencies with materials published by the Louisiana Pharmacy Board undermined the reliability that can be attached to his representations of contrition. Tr. 836-37. Likewise, even accepting the fact that he is not a pharmacist, to have so little professional curiosity in the regulatory requirements of the pharmacies he manages that he plead complete ignorance of the concept of red flags of diversion is hardly an attribute that can inspire confidence in the Agency's decision to re-entrust him with the weighty responsibility of a COR. Tr. 825-26. It is quite telling that his newly-generated compliance program was spearheaded by the MP West PIC, with virtually no input (at least none apparent on this record) from the PIC assigned to run the Respondent pharmacy. Tr. 830-32. More telling still is Mr. Vicellio's recognition that he relied on the knowledge and professionalism of the Respondent pharmacy's pharmacists and staff, but yet took no adverse action against any employee when it became obvious that they fell far short of their obligations. Tr. 836-37.[*D] There were no perceptible consequences to anyone responsible.

That is not to say that Mr. Vicellio presented as a wholly incredible witness; he certainly did not. There were many aspects of his testimony that were helpful and merit belief, such as important history and background information regarding the MP, Inc. pharmacies, the progress of the investigation, the impact on the Respondent pharmacy's operations, and the palpable regret he feels that the Respondent pharmacy (his mother-in-law's pharmacy), received an OSC/ISO from DEA to preserve public safety. Mr. Vicellio supplied testimony that was

[*D] Omitted for clarity.

detailed, internally consistent, and generally plausible, and overall, he presented as a generally credible witness with no pronounced contradictions from other sources in the record.

James W. Bryce, II

The Respondent presented the testimony of James W. Bryce who is and has been the pharmacist in charge (PIC) for MP West, serves as a staff pharmacist at the Respondent pharmacy, and was appointed by Mr. Vicellio to the newly-created position of compliance officer for MP, Inc. Tr. 873-74. Over Government objection,[116] Mr. Bryce was tendered[117] and accepted[118] as an expert witness in the areas of pharmacy and pharmacy practice in Louisiana. Tr. 889, 893.

Mr. Bryce testified that after some service as an Army medic, he enrolled in college, and in 1999 was awarded a degree in Pharmacy from what is now the University of Louisiana Monroe. Tr. 874-76. Mr. Bryce was first licensed to practice pharmacy in 1999, and has been continuously employed as a pharmacist from that time forward. Tr. 878.

Soon after securing his first pharmacist position as a line pharmacist as Walgreens, Mr. Bryce, by his recollection, was promoted within the company to a pharmacy manager and various positions of increased responsibility. Tr. 878-79. Mr. Bryce testified that after his time at Walgreens, he spent two years working at an independent mail-order pharmacy, and secured his current position from the late John LeTard at the Respondent pharmacy in 2012. Tr. 880-82.

Mr. Bryce described the high level of business routinely encountered at the Respondent pharmacy. He recalled specifically that his first day on the job was "quite eye-opening" and that in his twenty-one years of being a pharmacist he "had never seen a single pharmacy fill that many prescriptions." Tr. 885. He described the situation as "very intimidating at first" and characterized what he saw as "controlled chaos." *Id*. On an average day at the Respondent pharmacy, there would be four or five pharmacists working with six to eight pharmacy

---

[116] Tr. 891.
[117] Tr. 889.
[118] Tr. 894.

technicians. Tr. 886. In describing the staffing at the Respondent pharmacy, Mr. Bryce stated that, besides him, there are six pharmacists on duty at that store and another two on the job at MP West. Tr. 883. Shifts last the entire day for all pharmacists beginning at 8:30 a.m. and finishing at 6:00 p.m. *Id*. The pharmacy is closed on Sundays and has a shorter shift on Saturday from 8:30 a.m. to 4:00 p.m. Tr. 884. While every pharmacist does not work every day, on busier days all six are present. Tr. 883. Mr. Bryce described certain holiday weekends, especially the Monday after Labor Day Weekend, as "Black Friday" in which 1,700-1,800 or more prescriptions are filled in a single day. *Id*. In Mr. Bryce's estimation, on a typical day before the ISO, the Respondent pharmacy would fill approximately 1,000 prescriptions. Tr. 884.

Mr. Bryce testified that the position of compliance officer was created by the MP, Inc. in response to the ISO, and that he is the first person to hold the job. Tr. 887-888. Before the ISO, the Respondent pharmacy had no procedures, written or otherwise, for responding to diversion red flags. Tr. 895-96. Mr. Bryce acknowledged that he is not, and has never been the PIC at the Respondent pharmacy, a position that is, and at all times relevant to these proceedings has been, held by Charles Blaine Fontenot, who was not called as a witness by the Respondent.[119] Tr. 896. Mr. Bryce did not know why Mr. Fontenot was not present for the hearing or why he was not called as a witness. Tr. 897-98. Even though Mr. Fontenot is still the PIC for the Respondent pharmacy, there is no indication in the record that the Respondent pharmacy PIC was involved in the post-ISO procedures, and none that Mr. Bryce has been involved with the pre-ISO procedures at the Respondent pharmacy. Tr. 899. In the absence of an established policy (that is, prior to the ISO), it was for "[e]ach pharmacist, up to their discretion" how to handle a red flag. *Id*. Pharmacists also did not document resolution of any red flags. *Id*. [Omitted for brevity.]

[119] No explanation was offered by the Respondent as to why PIC Fontenot was not called as a witness, and the record revealed no indication of any issue regarding the availability of the Respondent pharmacy PIC, or any issue that would make him unamenable to process. Tr. 897-98, 1063-64.

Mr. Bryce admits that the pharmacy's documentation was "one hundred percent lacking in certain areas" and that where there was documentation, it was more akin to "internal recordkeeping." *Id*. The pharmacy kept something that Mr. Bryce referred to as the "due diligence binder" to document instances when prescriptions were not filled "in anticipation of having problems." Tr. 899-900. In terms of how it was used, Mr. Bryce said that he and the other pharmacists would "add stuff" to the binder if there was an issue with a prescription. Tr. 901. This single voluminous binder was not in alphabetical order or organized in a way where the pharmacists could reliably keep track of problematic prescriptions. *Id*. He stated that when a pharmacist accessed this binder, it was generally to put something in it. Tr. 902. He could not recall for certain whether he ever accessed the binder in deciding whether or not fill a particular prescription stating that sometimes he would "put certain items in there that triggered a memory of a situation." Tr. 903. Thus, it appears that every time a pharmacist at the Respondent pharmacy declined to fill a controlled substance prescription, a copy of the prescription was placed (in no particular order) into a binder and mostly ignored and forgotten. Tr. 901-03. As described, it seems clear that the "due diligence" file had very little do to with any diligence due, but was essentially a vessel created to store declined scrips in no order that was in any way amenable to retrieval or even monitoring. Tr. 900-04. [Omitted for brevity.]

Mr. Bryce noted that he and the other pharmacists "should have documented more in the computer system" but they failed to. Tr. 901. He added that since the ISO, he has "definitely learned a lot" about when and how documentation should occur. Tr. 900. He surmised that part of the reason why he was put in charge of compliance was his "willingness to hold people's feet to the fire" in following the new procedures. *Id*. According to Mr. Bryce, the computer system that the pharmacy now uses (Pioneer) tracks the identity of the pharmacist who dispensed a particular prescription. Tr. 911-13. Mr. Bryce noted his obligations under the Louisiana Administrative Code[120] to keep records of dispensing events. Tr. 911-12.

---

[120] This tribunal took official notice of the Louisiana Administrative Code § 1123. Tr. 914-15.

According to Mr. Bryce, even prior to the ISO, the Respondent pharmacy would refuse to fill a prescription if upon checking the PMP it was clear that the patient was filling prescriptions for controlled substances at other pharmacies. Tr. 928. Mr. Bryce described using the PMP to prevent "pharmacy hopping" or "doctor shopping". *Id*. The Respondent pharmacy has also refused to fill prescriptions for pain medication that did not come from a pain specialist. Tr. 929. Mr. Bryce explained that if the patient profile and the PMP data both showed that a patient was receiving pain medication from a physician who was not a pain specialist, oncologist, hospice specialist, or physical rehabilitation specialist, the pharmacists at the Respondent pharmacy would refuse to fill the prescription and explain to the patient that they need to be seeing a specialist. Tr. 930. The Respondent pharmacy maintained no list of prescribers whose prescriptions it refused to fill, but eventually concluded that there was an issue with a single, local provider, Dr. GB, a practitioner whose name factored heavily in the Government's case. Tr. 931. Mr. Bryce stated that the pharmacists at the Respondent pharmacy were aware that Dr. GB was having potential criminal issues with the DEA and would "call daily" to see if Dr. GB's COR was still active. *Id*. Thus, it was not Dr. GB's pattern prescribing that ultimately black-listed him from the Respondent pharmacy, but his legal troubles with DEA and warnings from a wholesaler.[121] Tr. 1055. Mr. Bryce was likewise apparently unimpressed with any indicia that Nurse Practitioner (NP) AH was, as the Government's expert determined, a pattern prescriber because he was familiar with her prescribing. Tr. 1034-40. Mr. Bryce discounted the evidence of NP AH's pattern prescribing, with the assurance that he is "familiar with her practice and her prescribing abilities." Tr. 1038. The witness provided the following explanation about the opinions he has formed in his community about prescribers, including NP AH:

[121] There is no indication in the record that Dr. GB's on-again-off-again DEA registration status provided any sort of a clue to the Respondent's pharmacists and staff that dispensing controlled substances for this prescriber might be problematic. It seems that so long as Dr. GB held a current registration on the day the prescription was presented, his patients could fill any number of prescriptions at the Respondent pharmacy. The record is unclear as to whether any of the written materials disseminated by the Louisiana Pharmacy Board specifically informed its regulated community that continuing to dispense for a practitioner who keeps losing and regaining his DEA registration on a day-by-day basis could potentially raise concerns for a pharmacist.

> I would say that [our opinions on reputation] are reliable opinions that we have on them. So we get a feel as far as whether we would trust them personally as well. Because it's our family, friends and our neighbors that are going to these prescribers, for the most part.

Tr. 1040.

On the issue of pharmacy shopping, Mr. Bryce allowed that in the past when he has encountered situations where Respondent pharmacy customers were getting controlled substance prescriptions dispensed to them at multiple pharmacies, he would insist that all controlled substance prescriptions be filled at the Respondent pharmacy. Tr. 932. Mr. Bryce testified that he was involved in Medication Therapy Management (MTM) as part of managing Medicare Part D plans. Tr. 933. He stated that Medicare would send lists of patients who needed a complete medication review. *Id*. Mr. Bryce would review the patients' medications with them and often explain to them, if only pain medications were on file with the Respondent pharmacy, that unless they filled all of their prescriptions at his pharmacy, they could not continue filling those customers' pain medications. *Id*. Mr. Bryce testified that he was able to ascertain that pharmacists at the Respondent pharmacy queried the state PMP system over 18,000 times between 2016 and 2019. Tr. 934. Mr. Bryce stated that checking the PMP prior to dispensing all controlled substances is now a requirement under the new MP, Inc. post-ISO protocols, and that this is a step beyond what is required under state law. Tr. 935-36.

Mr. Bryce stated the new post-ISO procedure requires the pharmacists to make a notation on the hard copy of a declined controlled substance prescription, and the declined, annotated prescription must be scanned into the Respondent pharmacy's computer system. Tr. 938-39. He further explained that hard copies of this information are currently in a box that he needs to alphabetize, but the electronic information is available with the patient profile. Tr. 939. The new Pioneer software brings up a comments section anytime a prescription is accessed which allows the pharmacist to document any issues. Tr. 941. Under the post-ISO policies, the Respondent pharmacy also will no longer fill prescriptions where there is a morphine milligram equivalent (MME) greater than 90 without written prior authorization. Tr. 942. As far as Mr.

Bryce understands, a comment section is not generated on a patient profile until a comment is entered. Tr. 943. Mr. Bryce estimates that around fifteen percent of the prescriptions that the Respondent pharmacy filled during the period referenced in the ISO were for controlled substances. Tr. 945. He confirmed that this information was of interest to the Respondent pharmacy's wholesalers because they preferred their customers to remain within a certain ratio. Tr. 946. Mr. Bryce indicated that he now understands certain combinations of controlled substances, including the "trinity," to be a "hard stop" or unresolvable red flag. Tr. 950. He also indicated that prior to the ISO, the pharmacy's software did not register the combination of an opioid, a benzodiazepine, and carisoprodol as problematic and flag it accordingly. Tr. 952. The pharmacists now have the ability to flag that combination for individual patients. Tr. 952-53. They now "won't touch a Soma[122] prescription with a ten-foot pole." Tr. 953.

Under the post-ISO procedures, if a prescription is not filled, the pharmacist will make a copy of it, log it in the PMP, and return the prescription to the patient unless the prescribing physician cancels it. *Id*. However, they will make a notation on the prescription as a means of notifying the next pharmacy where they may attempt to fill it. Tr. 954. Mr. Bryce created the new policies and procedures which are now in effect at MP West, over the weekend (that is, over one weekend) after the ISO was served on the Respondent pharmacy. Tr. 957. He decided that MP, Inc. pharmacies should no longer fill prescriptions from Dr. GB, because one of their wholesalers indicated that they would no longer do business with them if they continued to fill his prescriptions. Tr. 957, 1055.

Mr. Bryce explained how MME levels would be factored into dispensing decisions in the post-ISO protocol. For an MME range of zero to fifty, the pharmacist will look at the frequency of refills, which pharmacies the patient has patronized, and the prescribing physician. Tr. 961. For MME ranges between fifty and ninety, the prescription must be from a specialist, and a PMP report must be generated. Tr. 959, 961. For MMEs over ninety, all of the above precautions are

[122] Soma is a common brand name for carisoprodol.

taken but end-of-life palliative care is given "a little more leeway." Tr. 962. Mr. Bryce described MMEs over ninety as a "hard stop" meaning that more monitoring and discussion with the patient is required. *Id*. When faxing the prescriber a prior authorization form, a copy of the patient's PMP report is also sent as a way of confirming that the doctor is intending to prescribe a given MME. Tr. 964-965. The pharmacists are instructed to inform the prescribing physician that the prescription will not be filled until they fill out the prior authorization form and send it back to the pharmacy. Tr. 965. Mr. Bryce got a prior authorization form from the Louisiana Pharmacy Board. *Id*.

Mr. Bryce mentioned that other pharmacists in the area have contacted him about the post-ISO procedures and that some of those pharmacists have indicated (to him) that he has a reputation in the Baton Rouge area pharmacy community as a "hard-ass." Tr. 969. He admitted that prior to the ISO, the Respondent pharmacy was filling "trinity" cocktail prescriptions, a practice which he now has concluded, in his new, enlightened estimation, "we should never have done." Tr. 975. He stated that "even though it wasn't reported to us through any state means," he now understands[*E] he cannot fill prescriptions of this type. *Id*. He recounted that he and the other pharmacists at the Respondent pharmacy knew, for example, customer JMB who had been in an accident and was prescribed the trinity cocktail as part of treatment for injuries. Tr. 977. Because the Respondent pharmacy staff had some measure of an existing relationship with customer JMB, abuse or diversion was not suspected, and the medications were dispensed. *Id*. The tenor of Mr. Bryce's testimony[*F] in this regard gave the clear impression that he feels that the decision to dispense the trinity to JMB was not incorrect based on the Respondent pharmacy's understanding of the customer and his injuries, but that the pharmacy will simply no

---

[*E] Omitted for clarity.

[*F] Because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings regarding demeanor set forth in his recommended decision are entitled to significant deference. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951); *Jeffery J. Becker, D.D.S., and Jeffery J. Becker, D.D.S., Affordable Care*, 77 Fed. Reg. 72,387, 72,403 (2012). I find the Chief ALJ's characterization of Respondent's reaction in making these statements to be important in this case, where, as I have addressed more thoroughly *infra*, at Respondent's Exceptions, Respondent's witnesses have made general statements that seem to accept full responsibility while also making statements that tend to undermine that acceptance of responsibility.

longer dispense this combination because this is the only way (reason and judgment notwithstanding) to comply with federal law.

Like Mr. Vicellio, Mr. Bryce found it significant that the Louisiana Pharmacy Board has not put out any information about the trinity cocktail in their published literature, but (accurately) conceded that this lack of information did not excuse the Respondent pharmacy's failures in this regard. Tr. 977-78. Mr. Bryce further explained that the Texas Board of Pharmacy publications do provide, in Mr. Bryce's view, a much more thorough treatment of this issue.[123] Tr. 978. Regarding what Mr. Bryce (like Mr. Vicellio) perceives as a failure on the part of the Louisiana Pharmacy Board with respect to the absence of red flag treatment in its literature, he offered that the Board had "nothing published, and once again, [he] wish[ed] they would emulate what the Texas [Pharmacy] Board has done." Tr. 979. Mr. Bryce stated that the ISO experience has prompted him to become more involved in the Louisiana pharmacy community because "if neighboring states are providing this information to their pharmacists, it should definitely be available" "even though it's still no excuse for us filling [controlled substances in the face of diversion red flags]." *Id*. He stated that he knows the trinity cocktail is filled at other pharmacies in the area. *Id*. In fact, he is aware that customers who formerly filled such prescriptions at the Respondent pharmacy are now filling them elsewhere. *Id*.

Mr. Bryce also agreed that combination prescribing of an opioid with a benzodiazepine is "definitely a concern" to a patient's health. Tr. 980. He stated that prior to the ISO, this was a "common combination" that the pharmacy would see and now acknowledges that dispensing this combination [without documenting warnings to the patient] was "a violation of our corresponding responsibility," but his concession in this regard is hardly unqualified. *Id*. Mr. Bryce's admission that Respondent pharmacy personnel "did not document our warnings to the

[123] Mr. Bryce was never offered or accepted as an expert in the controlled substance prescribing standards in Texas. Based on his background as represented, there is no basis upon which to find an opinion as to his competence to speak to Texas law or controlled substance dispensing in Texas. In the absence of objection, Mr. Bryce provided an affirmative answer to the question of whether he had "seen [or] become exposed to the Texas Board of Pharmacy [] in terms of [] the information that it was passing out to its members." Tr. 978.

patient or the prescriber," is interesting because the record is devoid of any indication that such warnings were issued in any manner.[*G] *Id.* The witness's answer arguably supplies the (unsupported) impression that such warnings were given, but not documented.

According to the Respondent pharmacy's post-ISO procedures, carisoprodol will not be filled at all.[124] Tr. 982. With respect to combinations of opioids and benzodiazepines, Mr. Bryce is apparently unconvinced that all such combinations constitute diversion red flags that require scrutiny on the part of a DEA-registered pharmacy. Tr. 985, 989. According to Mr. Bryce, sometimes these prescription combinations can emanate from two different prescribers. Tr. 985. For example, sometimes a primary care provider will prescribe the benzodiazepine and a pain management specialist will prescribe the opioid such that the patient is not necessarily "doctor shopping." Tr. 985. The witness explained that following the implementation of the post-ISO policies that require prescriber contact, multiple prescribers have discontinued benzodiazepine prescriptions. Tr. 986-87. Under the Respondent's post-ISO polices, if this combination is dispensed, a print-out of the FDA's warning about this combination gets attached to the patient's prescription package. Tr. 987-88. Mr. Bryce stated that his interpretation of the FDA guidance was that there was no intended "hard stop" to trinity combination prescribing, and that based on an article he read in the Journal of the American Medical Association (JAMA), there has been only a modest national decline in prescribing combinations of opioids and benzodiazepines since the publication of the black box warning. Tr. 989. Thus, on the one hand, Mr. Bryce acknowledges that the dispensing of trinity-combination prescriptions is problematic,[125] but on the other, he cites authority and his own conclusions for the proposition that the black box warning was not a definitive statement,[126] and had a negligible impact on professional

---

[*G] Edits were made to this sentence to conform to the insertion in the previous sentence.
[124] This new policy is puzzling. The record contains no citation as to why declining to dispense an FDA-approved, DEA-controlled medication, such as carisoprodol, would render a registrant somehow in greater compliance. If anything, this policy suggests that the Respondent pharmacy and its staff are essentially throwing up their hands and banning the filling of potentially legitimate prescriptions based presumably on a lack of ability to discern legitimate carisoprodol prescriptions from illegitimate ones.
[125] Tr. 1061.
[126] Tr. 989.

prescribing. Indeed, much of Mr. Bryce's testimony strode an odd line between contextualizing and minimizing responsibility [omitted for brevity].

Regarding alternating payment methods, Mr. Bryce explained that among the first steps taken by a pharmacy upon presentation of a prescription is to input data and evaluate whether and to what extent available insurance will cover the cost of the medication. Tr. 993. According to Mr. Bryce, pharmacies "get [insurance] rejections all day long." *Id*. He further explained that on Medicare Part D and Medicaid plans, the coverage is very restrictive and the plans sometimes require prior authorizations or simply do not cover certain medications. Tr. 994. He explained that the Respondent pharmacy has a loyalty plan to compensate for high co-pays or gaps in insurance coverage. *Id*. Sometimes, customers will use the loyalty plan instead of insurance if it is less expensive. Tr. 992. However, he stated that even before the ISO, if a patient/customer asked the pharmacist to "run it off [their] insurance" that always "perked [their] ears up" and prompted the pharmacists to first run the prescription through insurance. Tr. 995. If a drug is not covered, the pharmacist will give the option to pay cash and use the loyalty program. Tr. 996. However, if a prior authorization is required for insurance coverage of a medication, the pharmacist will give the patient/customer the option of either waiting for the prior authorization to come through or paying cash. Tr. 996-97.

Mr. Bryce was apparently unwilling to confess error regarding all potential alternate payment method red flags cited by the Government's case-in-chief. In reference to patient LC, who filled two prescriptions for oxycodone-acetaminophen one week apart and used insurance for one but cash for the other, Mr. Bryce remarked that he (still) believes that no diversion red flag is indicated. Tr. 998. Rather, he stated that, to him, these are no more than indicia of an opioid naïve patient or an insurance plan that will only pay for a seven day supply of opioids. Tr. 999. He indicated that this a common phenomenon. *Id*. He also stated that there was a recent change in Louisiana law limiting opioid prescriptions to opioid naïve patients to a seven day supply. *Id*. Otherwise, the prescriber must indicate on the prescription that the larger supply

is medically necessary. Tr. 999-1000. Regarding patient BB, who had two prescriptions filled close together for benzodiazepines, Mr. Bryce recounted that one of those prescriptions was from a cardiologist who routinely prescribes low doses of benzodiazepines to help patients with the anxiety of getting a stent procedure. Tr. 1005-06. Based on his knowledge of both the patient and the prescriber, Mr. Bryce does not believe that this situation (ever) presented as a red flag. Tr. 1006-07.

Mr. Bryce elaborated that in his entire time working at the Respondent pharmacy, he has never had even an hour pass without an insurance rejection. Tr. 1008. He further explained that employees at the Respondent pharmacy have access to a system called Appriss, which allows for the sharing of PMP data across state jurisdictions. Tr. 1010. If a patient comes in who is not local, the Respondent's pharmacists, in the post-ISO environment, will now run PMP data through Appriss to check the information from neighboring states. *Id*. Mr. Bryce described how more complete information, including PMP reports, will now be included in the new and improved due diligence file. Tr. 1014, 1018-25; Resp't Ex. 4 at 1-4. He additionally described how both pharmacies [omitted][*H] subscribe to an FDA publication called *Drug Facts and Comparisons* which lists [the recommended and maximum dosages of controlled substances].[127] Tr. 1032-34.

[*H] Respondent objected to the Chief ALJ's statement that Mr. Bryce, "described how both pharmacies **now** subscribe to an FDA publication called *Drug Facts and Comparisons* . . ." Resp Exceptions, at 13-15 (emphasis added). In a footnote, the Chief ALJ went on to say "it is bewildering to fathom why this important source only became available to the Respondent's pharmacists after the service of the ISO in this case." RD, at n. 127. As grounds for its objection, Respondent explained that the Chief ALJ incorrectly concluded that Respondent only started subscribing to the publication after the ISO. *Id.* As the relevant testimony occurred generally while Mr. Bryce was testifying regarding changes to Respondent's policies and procedures following the ISO and the testimony is not particularly clear on the issue, I understand how the Chief ALJ reached his conclusion. However, I credit Respondent's position that this was not the meaning of Mr. Bryce's testimony and I have made edits accordingly. The Respondent further objected that the publication's purpose is not to "list available treatments for various medical conditions," but to list "the recommended and maximum dosages for the controlled substances at issue." Resp Exceptions, at 15. I agree with Respondent on this point and I have made changes accordingly. However, these technical edits do not impact my decision in this matter and I still find that Respondent's remedial measures, particularly in light of Respondent's failure to unequivocally accept responsibility, are insufficient to for me to entrust Respondent with a registration.

[127] Omitted as set forth in *supra* n. *H.

He also admitted that he believes the Louisiana standard prior authorization form existed before the ISO, but he was not previously aware of it.[*I] Tr. 1057. He stated that he was previously aware that the drugs which constitute the trinity cocktail are all drugs of concern for abuse and diversion. Tr. 1061.

[Omitted for brevity.] He testified that a number of Respondent pharmacy patients who traveled long distances to fill their prescriptions at the Respondent pharmacy had been customers for many years. Tr. 1044-45. Mr. Bryce essentially chalked up distance prescribing as it pertained to the Respondent pharmacy as outside the realm of a legitimate red flag requiring analysis and documentation. In discussing the issue on the stand, Mr. Bryce provided his thought process:

> . . . I would assume the reason [the distance customers] like us is we do have great customer service. We know our patients when they come in, we try to have the medication they need. We are a busy pharmacy, we have high volume, but we take care of our customers.

Tr. 1044. Thus, to Mr. Bryce, it appears that he feels that the Respondent pharmacy was justified in its distance prescribing. It may have been a red flag for some pharmacies, but due to his self-described "great customer service," it was never an issue for the Respondent pharmacy. Presumably, ascribing to this view, this is just another circumstance where the DEA regulators got it wrong. [However, Mr. Bryce went on to testify that he "definitely accept[s] the distance as a potential red flag and [we should] definitely resolve it before we dispense any medications for them. And that can be handled with a discussion with a patient." Tr. 1046. Mr. Bryce, based on

---

[*I] Respondent, in its Exceptions, objected to the Chief "ALJ's finding regarding the prior authorization form's purpose." Resp Exceptions, at 16. The Exception proceeds to address an argument made by the Government in its Posthearing Brief that the form existed to help pharmacists resolve potential red flags. *Id.* The Exceptions explain the legislature's intent in creating the form, including the intended purpose of the form, and claim that "Medical Pharmacy is using this form in a creative way to fulfill its corresponding responsibilities, but there has never been a requirement for this form to be used to combat diversion and the form was not created for that purpose." *Id.* However, the Chief ALJ did not make any finding regarding the purpose of the prior authorization form. Therefore, instead of objecting to the RD, the Respondent appears to be responding to the Government's Posthearing Brief. Ultimately, I find that the Chief ALJ's finding accurately summarizes the testimony of Mr. Bryce. This Exception, even assuming the truth of the assertions therein, is irrelevant to and has no impact on my decision in this matter. The only relevance that this form has to this proceeding is whether Respondent's use of it now for the purpose Respondent has offered it, constitutes, in combination with other proposed measures, adequate remedial measures to demonstrate that I can entrust it with a registration, all of which is addressed below in the Sanction Section.

discussions he has had with his customers, provided examples of reasons why customers have filled prescriptions with Respondent despite living further away. Tr. 1042-47. Mr. Bryce testified that distance is "a resolvable red flag," Tr. 1047, but that the past failures to document the resolutions was "[a]bsolutely wrong. We since learned we should not, without the documentation to resolve the red flag, we should not have filled [the prescription] . . . . [a]nd that's . . . where we've failed and that's where we've made the adjustments to make sure that we had documentation on those red flags moving forward." Tr. 1048.]

Mr. Bryce presented as a generally credible witness in terms of the factual accuracy of some of the information he provided. [Omitted for clarity. However, several of his positions were contrary to what the Government's expert established as being the applicable usual course of professional practice.] Mr. Bryce seems to disagree to varying degrees that the Respondent pharmacy wrongfully dispensed in the face of distance prescribing[128] (they knew their customers), pattern prescribing[129] (they knew the prescribers and had positive opinions of them), alternating payment methods[130] (it is all really a cost-saving and an insurance issue), doctor shopping[131] (different specialists prescribe for different ailments), and in some cases trinity prescribing[132] (other pharmacies are still filling these drugs and the FDA never really called a "hard stop"). On numerous occasions, Mr. Bryce appeared to minimize the Respondent pharmacy's non-compliance with clear state and federal pharmacy standards, and at other times, by couching his testimony in terms of a simple failure to adequately document, gave the unsupported impression that insightful analysis of red flags was taking place but was regrettably not adequately documented.

Even beyond minimization, the testimony of Mr. Bryce (like that of Mr. Vicellio) repeatedly points to what he perceives as deficient guidance from the Louisiana Pharmacy

---

[128] Tr. 1044-45.
[129] Tr. 931, 1038-40.
[130] Tr. 992-97.
[131] Tr. 1005-07.
[132] Tr. 989.

Board, literally because it (apparently) does not invoke the magic words "red flag." Tr. 979. There appeared to be little recognition or understanding that markers for diversion have been present since pharmacists have been practicing their profession, and it was up to the pharmacists and staff at the Respondent pharmacy to act as the controlled substance gatekeepers by applying the principles that distinguish them from grocery store clerks. [Omitted for brevity.][133]

Astonishingly, Mr. Bryce insisted that as a pharmacist he was unaware that certain combinations of medications were dangerous and even described some of these dangerous combinations as "common." Tr. 980. Whether the Louisiana Pharmacy Board disseminated this information to his personal satisfaction or not, as a seasoned pharmacist Mr. Bryce and the rest of the Respondent pharmacy staff can reasonably have been expected to know (well before the issuance of the ISO in this case) that trinity combinations are dangerous and that they had a host of concrete obligations as practitioners in a highly-regulated industry. It is commendable that the Respondent pharmacy had awareness of its prescribers, took steps to help its customers, knew their ailments, knew some of their history, and even helped its customers in navigating ways to afford their medications. These are admirable attributes for any professional, community-based pharmacy. However, in his testimony Mr. Bryce often conflates the laudable and professional practice of a conscientious pharmacist knowing his patients and doctors, with exercising the care, analysis, and documentation attendant with his corresponding responsibility.

Taken as a whole, Mr. Bryce does not seem to appreciate that the pharmacy operation he oversees as compliance manager actually had that much of a serious problem. Mr. Bryce peppered his testimony with periodic statements of "100%" taking responsibility and glib mentions of being "wrong," but those statements were not entirely consistent with the content of his presentation. It is impossible and beyond the scope of this recommended decision to understand whether Mr. Bryce was motivated by pride in or loyalty to his place of employment, concern for potential tertiary liability, the professional reputation of the Respondent pharmacy

---

[133] [Omitted]

(and himself) in his community, or some other reason(s), but it is clear that his equivocations squarely undermined the value of his testimony for the continuation of the COR he was trying to save. Stated differently, if Mr. Bryce is convinced that the established red flags were not really red flags for this pharmacy, there would be no logical reason for him to insist on having those issues identified, analyzed, and resolved by his staff in the future. [Omitted for brevity.]

Even beyond Mr. Bryce's intermittent minimizing, the depth of the remedial steps outlined by this witness does not really enhance the Respondent pharmacy's position. Even fully crediting his account of matters, the hundreds of transgressions persuasively outlined by the Government in its case-in-chief was met here with a single weekend staff training session[134] and a 16-page bullet-point, large-character, document that can be charitably described as sophomoric and lacking in any serious analysis. Resp't Ex. 1; Resp't Ex. 2. Laudable policies regarding increased documentation and scanning requirements that are touted as state-of-the-art comprise a standard that should have been present from the outset, and no person associated with the Respondent pharmacy has been subject to a single consequence. On balance, Mr. Bryce's hyperbolic characterizations of the organization's efforts notwithstanding, the Respondent's efforts at remedial steps can be fairly characterized as underwhelming.

Other facts necessary for a disposition of this case are set forth in the balance of this recommended decision.

The Analysis

The Government seeks revocation based on its contention that the Respondent pharmacy, through its pharmacists and employees, has committed acts that would render its continued registration inconsistent with the public interest as provided in 21 U.S.C. §823(f). The gravamen of the Government's allegations and evidence in this case focuses on the Respondent's alleged

---

[134] To the extent that the Respondent's closing brief suggests that "[t]he pharmacy staff *has been receiving* training on these new procedures" (ALJ Ex. 20 at 7, ¶ 12) (emphasis supplied), that is not borne out by the evidence of record.-

(1) dereliction in exercising its corresponding responsibility in dispensing controlled substance prescriptions and (2) violation of federal and state laws relating to controlled substances.

The Respondent has assented to every factual stipulation offered by the Government in this matter. Despite these numerous stipulations, the Government offered additional evidence of dispensing events where red flags were present and not resolved. For its part, the Respondent, while facially acknowledging error, pushed back on some particulars of the Government's case and challenged the underlying justifications for numerous red flags of diversion (some of them long-established red flags) cited in support of the Government's petition for sanction. The Respondent also presented evidence on the issue of remedial steps.

Public Interest Determination: The Standard

Under 21 U.S.C. § 824(a)(4), the Agency may revoke the COR of a registrant if the registrant "has committed such acts as would render its registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). Congress has circumscribed the definition of public interest in this context by directing consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f).

"[T]hese factors are to be considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's COR should be revoked. *Id.*; *see Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Moreover, the Agency is "not required to make findings as to all of the factors," *Hoxie v. DEA*, 419 F.3d 477, 482 (6th

Cir. 2005); *Morall*, 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . ." *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 462 (2009).

In adjudicating a revocation of a DEA COR, the DEA has the burden of proving that the requirements for the revocation it seeks are satisfied. 21 CFR § 1301.44(e). Where the Government has met this burden by making a *prima facie* case for revocation of a registrant's COR, the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Med. Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8236 (2010); *accord Krishna-Iyer*, 74 Fed. Reg. at 464 n.8. In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.*, 78 Fed. Reg. 38,363, 38,364, 38,385 (2013).

Normal hardships to the registrant, and even to the surrounding community, which are attendant upon lack of registration, are not a relevant consideration. *See Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66,972, 66,972-73 (2011); *Gregory D. Owens, D.D.S.*, 74 Fed. Reg. 36,751, 36,757 (2009). Further, the Agency's conclusion that "past performance is the best predictor of future

performance" has been sustained on review in the courts, *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie*, 419 F.3d at 483; *see also Ronald Lynch, M.D.*, 75 Fed. Reg. 78745, 78754 (2010) (holding that the respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.*, 75 Fed. Reg. 66,138, 66,140, 66,145, 66148 (2010); *George C. Aycock, M.D.*, 74 Fed. Reg. 17,529, 17,543 (2009); *Krishna-Iyer*, 74 Fed. Reg. at 463; *Steven M. Abbadessa, D.O.*, 74 Fed. Reg. 10,077, 10,078 (2009); *Med. Shoppe-Jonesborough*, 73 Fed. Reg. at 387.

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman v. SEC*, 450 U.S. 91, 100-03 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie*, 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz v. U.S. Dep't of Justice*, 873 F.2d 1089, 1092 (8th Cir. 1989), all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007); *see Humphreys v. DEA*, 96 F.3d 658, 663 (3d Cir. 1996). [Omitted for brevity.]

[Omitted for brevity.] It is well settled that, because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *see Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Agency's final decision. *Morall*, 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the

exercise of that discretion. 5 U.S.C. § 557(b); *River Forest Pharmacy, Inc. v. DEA*, 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a) (1947).

Factors 2 and 4: The Respondent's Experience Dispensing Controlled Substances and Compliance with Federal, State, and Local Law

The Government has founded its theory for sanction exclusively on Public Interest Factors 2 and 4, and it is to those two factors that the evidence of record relates.[135]

Applying the record evidence to Factor 2 (experience in dispensing controlled substances) in accordance with Agency precedent,[136] the Respondent is operated by MP, Inc., and has been licensed in Louisiana since 1968. Tr. 802, 805. No evidence was introduced regarding any basis upon which to characterize its level of compliance prior to the allegations that form the basis of this litigation.

The lion's share of the evidence presented in this litigation is most readily considered under Factor 4 (compliance with laws related to controlled substances). To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner

---

[135] The record contains no recommendation from any state licensing board or professional disciplinary authority (Factor 1). [Where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.*, 76 Fed. Reg. 19,434, 19,444 (2011) ("The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.").] Similarly, there is no record evidence of a conviction record relating to regulated activity (Factor 3). Even apart from the fact that the plain language of this factor does not appear to emphasize the absence of such a conviction record, myriad considerations are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities which lessen the logical impact of the absence of such a record. *See Robert L. Dougherty, M.D.*, 76 Fed. Reg. 16,823, 16,833 n.13 (2011); *Dewey C. MacKay, M.D.*, 75 Fed. Reg. 49,956, 49,973 (2010) ("[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry."), aff'd, *MacKay v. DEA*, 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.*, 74 Fed. Reg. 6056, 6057 n.2 (2009). Therefore, the absence of criminal convictions militates neither for nor against the revocation sought by the Government. Since the Government's allegations and evidence fit squarely within the parameters of Factors 2 and 4 and do not raise "other conduct which may threaten the public health and safety," (Factor 5) Factor 5 militates neither for nor against the sanction sought by the Government in this case.

[136] *JM Pharmacy*, 80 Fed. Reg. at 28,667 n.2; *Krishna-Iyer*, 74 Fed. Reg. at 462.

authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). Under the regulations, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR § 1306.04(a).[*J] The pharmacy registrant's responsibility under the regulations is not coextensive or identical to the duties imposed upon a prescriber, but rather, it is a *corresponding* one. 21 CFR § 1306.04(a); *see Tewelde v. Louisiana Bd. of Pharmacy*, 93 So.3d 801, 810 (La.App. 1 Cir. 2012) (affirming that Louisiana pharmacies are required to adhere to the corresponding responsibility requirements imposed by federal as well as state law). The regulation does not require the pharmacist to practice medicine; it instead imposes the responsibility to decline to dispense based upon an order that purports to be a prescription, but may not be, because evidence (either apparent on the prescription or attendant to the presentation of that prescription) would lead a reasonable pharmacist to suspect that the practitioner issued the prescription outside the scope of legitimate medical practice. *E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,157 n.30 (2010).[*K]

[According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR § 1306.04(a). While the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

> An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. § 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

[*J] Omitted to reduce repetition with added text. *See infra* n. *L.
[*K] Omitted to reduce repetition with added text. *See infra* n. *L.

Id. "The language in 21 CFR § 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons." *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990) (citing United *States v. Hayes*, 595 F.2d 258 (5th Cir. 1979), *cert. denied*, 444 U.S. 866 (1979); *United States v. Henry*, 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

To prove a pharmacist violated her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR § 1306.04(a) ("[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.") (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." *Bertolino*, 55 Fed. Reg. at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.*, 80 Fed. Reg. 28,667, 28,670-72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise "common sense and professional judgment" when filling a prescription issued by a physician. *Bertolino*, 55 Fed. Reg. at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.*; *Medicine Shoppe-Jonesborough*, 300 F. App'x 409, 412 (6th Cir. 2008) ("When pharmacists' suspicions

are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.").

Finally, "[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself." *Holiday CVS*, 77 Fed. Reg. at 62,341 (citing *Med. Shoppe—Jonesborough*, 73 Fed. Reg. at 384; *United Prescription Servs., Inc.*, 72 Fed. Reg. 50,397, 50,407-08 (2007); *EZRX, L.L.C.*, 69 Fed. Reg. 63,178, 63,181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 Fed. Reg. 61,613, 61,617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 Fed. Reg. 64,921, 64,924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.*, 69 Fed. Reg. at 63,181; *Plaza Pharmacy*, 53 Fed. Reg. 36,910, 36,911 (1988). Similarly, "[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself." *Holiday CVS*, 77 Fed. Reg. at 62,341.

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation for each of the patients at issue in this matter by filling prescriptions "without addressing or resolving multiple red flags of abuse or diversion." Govt Prehearing, at 22. Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR § 1306.04(a); *see, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10,876, 10,898, *pet. for rev. denied*, 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address

presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy*, 81 Fed. Reg. 49,816, 49,836-39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,507, 59,512-13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS*, 77 Fed. Reg. 62,316, 62,317-22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149, 66,163-65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Here, the Government established the presence of red flags on the prescriptions that Respondent pharmacy filled.][*L, 137]

The Louisiana Administrative Code largely mirrors the DEA regulations in that it specifies that a prescription for a controlled substance may only be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice." LA. Admin. Code tit. 46, § 2745(B)(1) (2019). Like the DEA version, the pharmacy's responsibility references penalties for knowingly dispensing "[a]n order purporting to be a prescription issued not in the usual course of professional treatment." *Id*. The State of Louisiana specifically requires the dispensing pharmacy "to ascertain that [a controlled substance] prescription was issued for a legitimate medical purpose." *Id*. at § 2747(E)(2)(a). Further, a pharmacist in Louisiana must "exercise sound professional judgment [in] ascertain[ing] the validity of a controlled substance prescription, and "[i]f, in the pharmacist's professional

---

[*L] The supplemented text in this section clarifies the analysis of a pharmacist's corresponding responsibility under 21 CFR § 1306.04(a).

[137] [Omitted.]

judgment, a prescription is not valid, [a controlled substance] prescription shall not be dispensed." *Id*. at § 2747(E)(2)(b).

In this case, the Government alleged and presented evidence that the Respondent pharmacy violated federal and state laws relating to controlled substances and filled prescriptions in a manner that violated its corresponding responsibility to ensure that controlled substances are dispensed only upon an effective prescription by failing to recognize and resolve red flags of diversion prior to dispensing. 21 CFR § 1306.04(a). Specifically, the Government alleges that the Respondent violated laws applicable to the dispensing of controlled substances by dispensing multiple controlled substances to multiple patients in the face of unresolved red flags indicating possible or even likely diversion. ALJ Ex. 1. Specifically, the Government alleges that the Respondent ignored diversion red flags based on: (1) dangerous combinations of controlled medications (cocktail prescribing and combination prescribing); (2) cash payments made by pharmacy customers for controlled medications; (3) patterns of controlled substance prescribing that should alert a reasonable pharmacist that the medications are not being prescribed for legitimate medical objectives; (3) long distances between customers, prescribers, and the registrant pharmacy; and (4) controlled substance prescriptions issued at potencies and quantities that should alert a reasonable pharmacist that the medications are likely not being prescribed for legitimate medical objectives.

The CSA and its implementing regulations require that pharmacists only dispense prescriptions that are issued for a legitimate medical purpose in the usual course of professional practice. 21 CFR § 1306.04(a). While prescribers are responsible for writing only legally sound prescriptions, a corresponding responsibility rests with the pharmacist to refuse to fill prescriptions that are not valid. *Id.* Louisiana law imposes a similar responsibility and requires pharmacists to exercise sound professional judgment in dispensing and respond with "appropriate action" where a prescription presents signs of therapeutic duplication, possible

abuse/misuse, or inappropriate dosing. LA Admin. Code. tit. 46, Part LIII §§ 515, 2745(B)(1), 2747(E)(2)(a).

The stipulated facts and additional problematic dispensing events alleged by the Government point to a pattern and practice of dispensing dangerous controlled substances in the face of numerous red flags. The evidence of record demonstrates that on one hundred separate occasions, the Respondent pharmacy dispensed "cocktail" medications, that is, combinations of drugs that are known to be abused and diverted.[138] On an additional nineteen separate occasions, the Respondent pharmacy dispensed combinations of medications that posed serious risks to patients.[139] On seven occasions the Respondent pharmacy also dispensed controlled substances, where alternating payment methods were employed, and customers tendered cash for some medications and utilized insurance for others without any scrutiny from the Respondent pharmacy's pharmacists or staff.[140] The Respondent pharmacy filled pattern prescriptions from problematic prescribers on eighteen stipulated occasions and others highlighted by Dr. Ginsburg.[141] Its pharmacists additionally filled prescriptions for customers in the face of unresolved distance red flags.[142] Finally, the Respondent pharmacy filled prescriptions for quantities and strengths of drugs that posed a risk to the patients who would be taking them on twenty one separate occasions as well as others explained by Dr. Ginsburg without identifying the combinations as problematic and resolving and documenting any rationale.[143]

The Respondent stipulated to one hundred occasions where it dispensed cocktail medications and dangerous combinations of medications, including but not limited to the

---

[138] *See* Stip. 3(a)-(d); Stip. 4(a)-(d), (h)-(f), (i)-(m), (p)-(yy); Stip. 5(a)-(g); Stip. 6(a)-(ddd); Stip. 7(a)-(z); Stip. 8(a)-(dd).
[139] *See* Stip. 4(rr)-(tt); Stip. 9(a)-(c); Stip. 10(a)-(f); Stip. 11(a)-(c); Stip. 12(a)-(b); Stip. 13(a)-(c); Stip. 14(c)-(k); Stip. 15(a)-(b); Stip. 16(a)-(c); Stip. 17(a)-(d).
[140] *See* Stip. 4(n)-(o); Stip. 4(rr)-(tt); Stip. 18(a)-(b); Stip. 19(a)-(b); Stip. 20(a)-(b); Stip. 21(a)-(b).
[141] *See* Stip. 4(rr)-(tt); Stip. 9(a)-(b); Stip. 10(a)-(b); Stip. 14(a)-(b); Stip. 18(a)-(b); Stip. 22(a)-(b); Stip. 23(a)-(b); Stip. 24(a)-(b); Stip. 25(b); Stip. 26(a)-(c); Stip. 27(a)-(b); Stip. 28(a); Stip. 29(a)-(b); Stip. 30(a)-(b); Stip. 31(a)-(b); Tr. 509-11; Gov't Ex. 39 at 1; Tr. 519-22; Gov't Exs. 42 at 1, 43 at 2; Tr. 528-35; Gov't Exs. 56 at 1, 57 at 2, 58 at 1, 59 at 1.
[142] Tr. 295-97.
[143] *See* Stip. 10 (a)-(b); Stip. 14(l); Stip. 18(a)-(b); Stip. 22(a)-(b); Stip. 23(a)-(b); Stip. 24(a)-(b); Stip. 25(b); Stip. 26(a)-(c); Stip. 37; Stip. 38; Stip. 39; Stip. 40; Stip. 41; Stip. 42; Stip. 43; Stip. 44; Stip. 45; Stip. 46; Tr. 482-84, 493-94, 496-97; Gov't Exs. 50 at 1.

"trinity" cocktail of an opioid, a benzodiazepine, and carisoprodol.[144] DI credibly testified that the PMP data from the Respondent pharmacy demonstrated that a high quantity of "trinity" cocktail prescriptions were being dispensed. Tr. 71. Dr. Ginsburg persuasively testified that while not a violation on its own, such prescriptions presented red flags that would require documented resolution in order for the Respondent pharmacy to comply with its corresponding responsibility. Tr. 308, 312, 314, 316-20, 322, 325, 330, 336-43, 347-51, 358, 359-66, 376-88, 392-93, 395-96, 550-52. In response to administrative subpoenas, the Respondent pharmacy did not produce patient records or profiles that provided any identification or resolution of any red flags identified prior to dispensing. Tr. 53-54; Gov't. Ex. 64; Gov't. Ex. 66. Mr. Bryce testified that he and the other pharmacists "should have documented more in the computer system" but they failed to. Tr. 900. Mr. Vicellio further indicated that where records were not turned over to the DEA, it was because they did not exist. Tr. 862.

During the course of his guarded testimony, Mr. Bryce seemed intent on giving the impression that the root of the problem here was limited to inadequate documentation. To be clear, the lack of documentation during the period in question was certainly deplorable [and outside the usual course of professional practice], but the transgressions of the Respondent pharmacy were not limited to documentation deficiencies. If this case were limited to a failure to document (here serious enough to warrant a sanction on its own), the Respondent could easily have furnished the testimony of the Respondent pharmacy's PIC, Mr. Fontenot, to explain that the proper analyses had been performed by his line pharmacists but not documented. That did not happen, so no one really knows what the PIC and his line pharmacists at the Respondent pharmacy were thinking.[*M]

---

[144] *See* Stip. 3(a)-(d); Stip. 4(a)-(d), (h)-(f), (i)-(m), (p)-(yy); Stip. 5(a)-(g); Stip. 6(a)-(ddd); Stip. 7(a)-(z); Stip. 8(a)-(dd).

[*M] [Text relocated.] No explanation was offered by the Respondent as to why the PIC was not called as a witness, and the record revealed no indication of any issue regarding the availability of the Respondent pharmacy PIC, or any issue that would make him unamenable to process. Tr. 897-98, 1063-64. The tribunal may, as a matter of discretion, draw an adverse inference from Mr. Fontenot's absence from the proceedings. Where a party fails to produce relevant evidence within its control, it is appropriate to draw an adverse inference. *Int'l Union (UAW) v.*

Regarding alternating payments, the Government alleged numerous occasions on which the Respondent pharmacy filled prescriptions where pharmacy customers used multiple payment methods to cover different prescriptions. Tr. 297-98, 398-99. Dr. Ginsburg persuasively testified that this a red flag requiring resolution prior to dispensing because a patient electing such payment methods may be attempting to shield certain prescriptions from scrutiny by insurance. Tr. 298-99. No reason was offered for this practice other than an explanation of attempts to save customers money through the use of the Respondent's loyalty plan. Tr. 992-96. The Respondent's argument here is facially appealing but analytically bankrupt. To the extent that a red flag of diversion reveals itself during a controlled substance dispensing event, it is incumbent upon the pharmacy registrant to identify the red flag and resolve the issue prior to dispensing the medication. The holder of a DEA pharmacy registration bears the obligation, by the exercise of its corresponding responsibility, to act as a gatekeeper to the closed controlled-substance system. Responsible actions by the registrant protect the customer from dangerous abuse and the public from wholesale diversion of powerful, dangerous drugs. Here, the Respondent argues that in the face of this potential red flag, without any circumspection, it evaluated a method whereby the drugs can be dispensed in the cheapest way possible. A good monetary deal for the prescription holder is not necessarily synonymous with the responsible exercise of a registrant's obligations to discharge its corresponding responsibility. [Furthermore,

---

NLRB, 459 F.2d 1329, 1338 (D.C. Cir. 1972) (holding that NLRB committed reversible error by declining to apply the adverse inference rule where one of the parties had relevant evidence within his control which he failed to produce.); *see also Callahan v. Schultz*, 783 F.2d 1543, 1545 (11th Cir. 1986) (applying the adverse inference rule against the Government in quashing an IRS summons.); *Pharmacy Doctors Enterprises, d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10,876, 10,899 (2018). At the hearing, both sides were put on notice that the tribunal was considering the issue of an adverse inference. Tr. 1077-78. [The Chief ALJ concluded], as an evidentiary matter, [omitted] that if this witness had presented testimony, that testimony would have supported the proposition that not only did the Respondent pharmacy staff neglect to document the actions they took in response to red flags of potential diversion, but they also did not identify or analyze these red flags in any serious way. [I, however, do not find the drawing of an adverse inference to be necessary. The record evidence established, and Respondent has largely conceded, that not all red flags were resolved and in no instance was the potential resolution of any red flag documented. Accordingly, there is ample evidence without an adverse inference to establish that Respondent pharmacy issued these prescriptions outside the usual course of professional practice and in violation of its corresponding responsibility.]

even if Respondent had legitimate reasons why it was receiving different types of payments for controlled substance prescriptions, the resolution of this red flag was not documented anywhere.]

The Government established that the pharmacists at the Respondent pharmacy repeatedly filled prescriptions from prescribers who exhibited clear signs of being pattern prescribers. Dr. Ginsburg identified several prescribers who repeatedly prescribed the same combinations of high-dose opioids to many patients. Tr. 435, 502-04, 506-09. There were no documented attempts to resolve this red flag. Tr. 327, 329-31, 336-37, 550-52. Mr. Bryce further admitted that despite exhortation from one of the Respondent pharmacy's distributors, the pharmacy continued to fill prescriptions from Dr. GB. Tr. 931. He testified that the pharmacy would have to call frequently in order to confirm whether Dr. GB's DEA COR was still active, surely a sign of a problematic prescriber (even without threats from a distributor and before the issuance of the ISO in this case). *Id*. Regarding this red flag, the Respondent was aware that at least some of these prescriptions were problematic, dispensed them nonetheless, and made no attempt to verify if these prescriptions were issued for a legitimate medical purpose in the usual course of professional practice.

Dr. GB's prescriptions, among others that were filled by the Respondent pharmacy, presented potentially hazardous quantities and strengths of opioid and benzodiazepine medications. Tr. 435; Gov't Ex. 4 at 1. According to Dr. Ginsburg's uncontroverted testimony, the documentation provided by the Respondent pharmacy was insufficient to demonstrate resolution of this red flag. Tr. 502-03, 505-06, 512-16, 526, 535-38, 550-52. While Mr. Bryce indicated some steps that MP West has taken to better identify and resolve this red flag [in the future], he provided no explanation, beyond a bland expression of contrition, for why these prescriptions were filled. Tr. 952-62.

The evidence of record demonstrates that the Respondent has neglected its corresponding responsibility imposed by the CSA and the Louisiana Administrative Code. *See* 21 CFR § 1306.04(a) (establishing corresponding responsibility under the Controlled Substances Act);

Liddy's Pharmacy, 76 Fed. Reg. at 48895 (affirming that only lawful prescriptions may be dispensed); LA. Admin. Code tit. 46, § 2745(B)(1) (2019) (establishing corresponding responsibility under Louisiana state law). The Respondent, through its pharmacists and staff, demonstrably knew or had reason to know that these prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice. *See Med. Shoppe-Jonesborough*, 73 Fed. Reg. at 381 (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044 (1990)) (requiring a pharmacist to refuse to fill such prescriptions). By dispensing these prescriptions despite knowing that they were potentially dangerous and failing to investigate further, the Respondent pharmacy failed to follow its legal responsibilities. *See Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. at 24530 (quoting *Ralph J. Bertolino*, 55 Fed. Reg. 4729, 4730 (1990) (stating that a pharmacist may not "close his eyes and thereby avoid [actual] knowledge" of possible abuse or diversion).

[Omitted for clarity. The record evidence establishes that] the prescriptions detailed in the Government's evidence and agreed stipulations [were issued] without resolving the red flag(s) presented and documenting that resolution.[145] The red flags detailed above required the Respondent and its pharmacists to question these prescriptions and they did not. *See Bertolino*, 55 Fed. Reg. at 4730 (requiring pharmacists to question prescriptions that present red flags for abuse or diversion). [Omitted for brevity.]

The quantity of questionable prescriptions that the Respondent pharmacy filled, coupled with the virtual absence of attempts, documented or not, to resolve red flags points inexorably and conclusively toward willful blindness. First, the Respondent, in business for decades, maintained no formal procedures whatsoever for responding to red flags. Tr. 833. Further, the evidence of record demonstrates an astonishing level of ignorance (sincere or not) among the Respondent's corporate officers and employees regarding their legal obligations. Mr. Vicellio testified that although he has been aware that operating a pharmacy is a highly-regulated activity,

---

[145] *See* Appendix. [Footnote was relocated.]

which requires careful and diligent adherence to federal and state laws and regulations, until the ISO he made no sustained effort to familiarize himself with these requirements and, as a non-pharmacist, assumed his pharmacy-trained employees would keep him out of trouble. Tr. 835-36. Mr. Bryce, the newly-appointed compliance officer, also admitted knowledge that many of these prescriptions presented dangerous combinations of drugs and [yet they were dispensed.][*N] Tr. 1061. [Omitted for brevity.] To be persuaded by the Respondent's case, it would be necessary to assume there was no way that professional pharmacists and pharmacy staff could be aware of their obligations to avoid wholesale drug diversion without the issuance of an ISO by DEA, or the use of the specific term "red flag" in the literature disseminated by the Louisiana Pharmacy Board.[146] The Respondent here, through its pharmacists, staff, and management, ran the busiest pharmacy in the local area, presided over "controlled chaos," and kept its foot on the gas until stopped by the DEA's ISO. [Omitted for brevity.]

[Accordingly, I find that Respondent has operated outside the usual course of professional practice (in violation of 21 CFR § 1306.06 and La. Admin Code tit. 46, Part LIII, §§ 2745(b)(1), 2747(E)(2)(a)) and in violation of its corresponding responsibility (in violation of 21 CFR § 1306.04(a) and La. Admin Code tit. 46, Part LIII, §§ 515, 2745(b)(1), 2747(E)(2)(a).] Based on the foregoing, the Government has made a *prima facie* case that the Respondent has committed acts which render its registration inconsistent with the public interest.[*O] Accordingly, all allegations enumerated in the OSC/ISO[147] are **SUSTAINED**.

[*N] Modified for clarity.

[146] ALJ Ex. 20 at 9.

[*O] For purposes of the imminent danger inquiry, my findings lead to the conclusion that Respondent has "fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant" under the CSA. 21 U.S.C. § 824(d)(2). The substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice established "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension" of Respondent's registration. *Id*. There was ample evidence introduced to establish that Respondent, without first resolving red flags, repeatedly dispensed combinations of medications that posed serious risks to patients. *See supra* n. 23. Thus, as I have found above, at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger.

[147] ALJ Ex. 1. At the hearing (Tr. 435-41, 774-91) and in its closing brief (ALJ Ex. 20 at 2-5), the Respondent lodged an objection as to notice. Specifically, the Respondent avers that the Government's charging document (ALJ Ex. 1 at 11, ¶ 12) and Prehearing Statement (ALJ Ex. 4 at 21-22) supplied a definition of pattern prescribing that is

[Sanction] [*P]

The evidence of record preponderantly establishes that the Respondent has committed a massive volume of acts which render its continued registration inconsistent with the public interest. *See* 21 CFR § 1301.44(e) (establishing the burden of proof in DEA administrative proceedings). Since the Government has met its burden in demonstrating that the revocation it seeks is proper, the Respondent must show that given the totality of the facts and circumstances revocation is not warranted. *See Med. Shoppe-Jonesborough*, 73 Fed. Reg. at 387. In order to rebut the Government's *prima facie* case, the Respondent must demonstrate not only an unequivocal acceptance of responsibility but also a demonstrable plan of action to avoid similar

---

at some variance with the definition utilized by the Government through its expert, Dr. Ginsburg. Specifically, the Respondent argues that the Government's noticed definition refers to a pattern of scrips issued by "a physician who regularly prescribes common drugs of abuse and diversion in the same dosages and quantities to many of his or her patients sharing the same surnames and/or addresses and uses the same diagnosis codes to justify these prescriptions." ALJ Ex. 4 at 21. The OSC/ISO in this case informs that "[p]attern prescribing refers to a practitioner who regularly prescribes common drugs of abuse or diversion in the same dosages and quantities to multiple patients where the patients often share the same surnames and/or addresses, and/or where the prescriber uses the same diagnosis codes to justify these prescriptions." ALJ Ex. 1 at 11, ¶ 12. The objection was overruled at the hearing (Tr. 439-40, 782-91), but the issue was timely raised and preserved for appeal. In the APA, Congress provided that an administratively-imposed sanction must be preceded by notice of, *inter alia*, "the matters of fact and law asserted." 5 U.S.C. 554(b)(3). The DEA regulations require the charging document to supply "a summary of the matters of fact and law asserted." 21 CFR § 1301.37(c). [Omitted for relevance.] This is not a close case. The Agency has long held that the parameters of its administrative hearings are circumscribed by the allegations in its charging documents and the prehearing statements filed by the parties. *See, e.g., Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48,887, 48,896 (2011); *CBS Wholesale Distribs.*, 74 Fed. Reg. 36,746, 36,750 (2009); *Darrell Risner, D.M.D., P.S.C.*, 61 Fed. Reg. 728, 730 (1996). Under the Agency's precedent, "[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law", *Clair L. Pettinger, M.D.,* 78 Fed. Reg. 61,591, 61,596 (2013), and "[t]he rules governing DEA hearings do not require the formality of amending a [charging document] to comply with the evidence." *Id.*; *Roy E. Berkowitz, M.D.*, 74 Fed. Reg. 36,758, 36,759-60 (2009). The Agency has interpreted the standard to be keystoned on whether the Respondent had notice that a subject "would be at issue in the proceeding." *Pharmacy Doctors,* 83 Fed. Reg. at 10,898. The Agency has declined to find inadequate notice, even where the Government has actually cited an errant provision of the regulations. *Wesley Pope, M.D.*, 82 Fed. Reg. 14,944, 14,946 (2017). Here, the charging document and Government's Prehearing Statement provided a definition of pattern prescribing with conjunctive terms and proceeded on a subset of its definition. The language in the charging document included "*many*" patients with the same surname and diagnosis codes (ALJ Ex. 1 at 11, ¶ 12) and the language in the Government's Prehearing Statement alleged that this was "*often*" the case. ALJ Ex. 4 at 21. It is unpersuasive to argue that the Respondent was fatally misled because some or even all of the pattern prescribing alleged by the Government failed to contain every potential attribute listed in the charging document and prehearing statement. Inclusion of all elements all pattern prescribing was not alleged by the plain language in either document. The Respondent received adequate notice that pattern prescribing was an issue in the case, and its objection in this regard is unfounded. In any event, even if every pattern prescribing allegation set forth by the OSC/ISO and the Government's Prehearing Statement were not sustained in this case, it would not alter the outcome. The remaining massive volume of misconduct alleged and preponderantly established by the Government even without any of the pattern prescribing alleged and established in this case would render the pattern prescribing evidence superfluous.

[*P] I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

conduct in the future. *Jeri Hassman, M.D.*, 75 Fed. Reg. 8236. It has accomplished neither objective.

Agency precedent is clear that a Respondent must "unequivocally admit fault" as opposed to a "generalized acceptance of responsibility." *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,510 (2014); *see also Lon F. Alexander, M.D.*, 82 Fed. Reg. 49,704, 49,728 (2017). To satisfy this burden, the Respondent must "show true remorse" or an "acknowledgment of wrongdoing." *Robert A. Leslie*, 68 Fed. Reg. 15,527, 15,528 (2003). The Agency has made it clear that unequivocal acceptance of responsibility is paramount for avoiding a sanction. *Robert L. Dougherty, M.D.*, 76 Fed. Reg. 16,823, 16,834 (2011) (citing *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 464 (2009)). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay v. DEA*, 664 F.3d 808, 822 (10th Cir. 2011).

The Respondent's incantations of "regret[]"[148] in this case are unconvincing and serve as something of a testament to the elevation of form over substance.[*Q] Simply put, the Government's *prima facie* case has not been rebutted. Words purporting to accept responsibility are planted into a mosaic of equivocation and qualification which, in this case, undermines any attempt to demonstrate that the Respondent understands what it did wrong in any meaningful way and diminishes confidence in its future performance as a registrant. To be sure, the Respondent assented to the Government's proposed stipulations,[149] but its case rested primarily on its pervasive view that every transgression was not really all that bad. ALJ Ex. 5 at 2. As detailed above, these stipulations include numerous dispensing events that presented one or more

---

[148] ALJ Ex. 4 at 23.

[*Q] Prior Agency decisions have made it clear that in order to avoid sanction once the Government has established a *prima facie* case, a registrant must do more than say the right thing on the stand and in filings. "The degree of acceptance of responsibility that is required does not hinge on the respondent uttering "magic words" of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator." *Jeffrey Stein, M.D.,* 84 Fed. Reg. 46,968, 49,973 (2019).

[149] ALJ Ex. 5 at 2.

unresolved red flags.[150] As discussed, *supra*, testimony from Mr. Vicellio and Mr. Bryce contained equal measures of purported admissions of wrongdoing and justifications about why the red flags should not be red flags, how even if the red flags were arguably valid they did not really apply to the instances involving the Respondent pharmacy, that even if the red flags did have some application, the offense was again, really not all that bad, and even if the offenses were bad, the Louisiana Pharmacy Board should have been more like Texas and included the words "red flag" in its guidance documents.

Mr. Bryce provided some lip service to contrition, but continually undermined those words by such propositions as distance prescribing was justified in this case because the Respondent's staff knew their customers,[151] pattern prescribing evidence was dispatched with the representation that the staff knew the prescribers, [152] alternative payment issues were dismissed by protestations that the pharmacy was simply trying to make life affordable for its customers,[153] doctor shopping was addressed with a lecture that different specialists prescribe for different ailments, and by Mr. Bryce's view of the facts, trinity prescribing could not have been so bad (only a "concern"[154]), because the FDA's guidance was never really a "hard stop," and trinity prescriptions, even after the black box warning, are still alive and well.[155] Perhaps the most discouraging of Mr. Bryce's equivocations was his adoption of Mr. Vicellio's theme that the Louisiana Pharmacy Board is somehow responsible for the Respondent's troubles, because unlike Texas, the Louisiana Pharmacy Board has not used the exact words "red flag."[156]

The Respondent's closing brief made it clear that its witnesses' acceptances of responsibility equivocations (as ubiquitous as they were) could not be easily dismissed as unartful or unintentional misstatements borne of the pressure of testifying at a hearing. In its

---

[150] *See* Appendix.
[151] Tr. 1044-45.
[152] Tr. 931, 1038-40.
[153] Tr. 992-97.
[154] Tr. 980.
[155] Tr. 987-89.
[156] Tr. 977.

brief, the Respondent prefixes its acceptance of flying through red flags of diversion by highlighting that "the Louisiana Board of Pharmacy has not identified th[e trinity] combination as involving a red flag (or discussed 'red flags' or officially acknowledged that there is such a thing for that matter) . . . ." ALJ Ex. 20 at 2. Elsewhere in its closing brief, in the course of challenging the credentials of the Government's expert, the Respondent makes the following point:

> The Louisiana Board of Pharmacy does not even mention the term "red flag" in any of its publications, policy statements or regulations, and that term is not used in the statutes governing pharmacy in Louisiana.

Id. at 9.[157] Similarly, the FDA black box warnings are dismissed as all but irrelevant because:

> The FDA never said any such thing about such a requirement being imposed upon pharmacists. There is nothing within the FDA's 2016 statement that states or suggests that a pharmacist should "carefully review" anything about the purpose for which these [trinity] prescriptions are issued.

Id. at 3. Thus, the Respondent, through its counsel, still actively takes the position that the FDA warnings about the potential perils attendant upon a particular combination of drugs should have no effect whatsoever on its pharmacists' dispensing practices, or even impact upon their analyses as professionals. The Respondent's closing brief echoes Mr. Bryce's dismissal of the danger by pointing out that "[t]here are literally millions of such [trinity] combinations of these two medications being prescribed every year, and the FDA's 2016 statement has not significantly reduced this number." *Id*.

The Respondent's brief likewise makes quick work of the red flag of alternative payment methods right before its incongruent purported acceptance of responsibility in the following way:

> Today, when all but one state has a PMP (including Louisiana) a patient could not avoid detection of doctor-shopping through this means, and there exist multiple commercial services which often provide a lower price for medications than is available through insurance—such services, such as Good RX advertise this feature. Many of the instances in which cash payments were used [by the Respondent pharmacy] occurred because the patient's health insurance would not

[157] Ironically, the Respondent, in its closing brief, appears to level criticism based on the fact that unlike Texas "in both Louisiana and federal law, the term 'pill mill' is at most a colloquial or slang term which is not used in any official way by either the Louisiana Board of Pharmacy or the [DEA], and is not found anywhere in Louisiana or federal statutory or regulatory law." *Id*. at 9. In light of the evidence as developed in this case, this observation, if assumed, *arguendo*, as valid, likely inures to the Respondent's benefit.

> pay for the medication, or would only pay for a portion of the prescription because the benefits available only covered a shorter period.

Id. at 4. The Respondent is apparently not concerned here either. The theory is that this should not even be a red flag for pharmacy registrants because the PMP will pick up the issue anyway.

There is likely no more telling argument set forth in the Respondent's brief than its handling of the DEA's exercise in investigatory lenity in allowing the on-hand controlled substances at the Respondent pharmacy to be transferred to MP West instead of seizing the drugs.[158] By the Respondent's reckoning, this discretionary act of forbearance at the execution of the ISO "is something that the [DEA] agents would not have done had they believed that the pharmacy's personnel were engaged in ongoing lawless behavior." *Id*. at 10. As it happens, the evidence here preponderantly and convincingly established that the Respondent's pharmacy personnel *were* in fact "engaged in ongoing lawless behavior." *Id*. It seems that it is the Respondent's managers who are unwilling to believe it, and this interpretation of events speaks volumes as to how an exercise in discretionary lenity in the Agency's final order would likely be viewed by the Respondent.

Notwithstanding the staggering volume of transgressions established by the record, the Respondent dismisses the number as "a very tiny percentage of the almost 800,000 prescriptions filled during the time period covered by the ISO." *Id*. at 20. The Respondent's acceptance of responsibility is narrowly tailored (consistent with the testimony of its witnesses) to "its improper filling of certain controlled substances including, in some instances, is failure to document the resolution of red flags." *Id*. at 2. Suffice to say, the Respondent has not supplied the Agency with an unequivocal acceptance of responsibility. More than that, it is clear that beyond equivocating, the Respondent somehow does not comprehend that it was wrong, and egregiously and voluminously so.

---

[158] 21 U.S.C. 824(f).

While the transgressions alleged and proved here are serious and numerous, it is arguable that a true, unequivocal acceptance of responsibility, coupled with a thoughtful plan of remedial action could have gone a long way to supporting a creditable case for sanction lenity. The Agency has frequently required unambiguous acceptance of responsibility and a remedial action plan as an essential component to avoid a sanction,[159] and in this case the reality that the Respondent, truly acknowledging no deficiencies that are immune from explanation, has limited its remedial action investments to increased documentation requirements, a single staff training session, a sixteen-page list of talking points, and stepping up internal documentation rules to a point where they should always have been. Neither the Respondent pharmacy PIC (who even yet remains the PIC), nor any other employee or manager received any form of discipline or consequence as a result of the wholesaling doling out of dangerous drugs for three years with reckless abandon. Tr. 836-37. In the Respondent's view, its pharmacists really did nothing wrong once the circumstances were explained. Although the Respondent put in place some improved documentation requirements, the remedial plan is by no means a thoughtful or comprehensive one, staff training is not ongoing, and in light of myriad excuses and explanations it is difficult to be confident that the Respondent and its staff would make responsible choices as a registrant in the future. [Omitted.][*R] Thus, in the face of a *prima facie* case, without the Respondent meeting the evidence with a convincing, unequivocal acceptance of responsibility and proposing thoughtful, concrete remedial measures geared toward avoiding future transgressions, the record supports the imposition of a sanction. That a sanction is supported does not end the inquiry, however.

In determining whether and to what extent imposing a sanction is appropriate,

---

[159] *Hassman*, 75 Fed. Reg. at 8236. [Edited the footnoted sentence for clarity.]

[*R] Respondent took exception to this text claiming that the Chief ALJ "transformed his 'difficult to be confident' finding into a finding that absent a registration sanction the agency would be 'creating a likelihood that it will be instituting new proceedings, charging the same conduct, soon thereafter.'" Resp Exceptions, at 8. I adopt the Chief ALJ's finding that it is difficult to be confident in Respondent's future compliance and therefore find that I cannot trust Respondent with a registration. I find that the Chief ALJ's further findings are irrelevant to my final decision in this case and do not impact my sanctions determination.

consideration must also be given to the Agency's interest in both specific and general deterrence and the egregiousness of the offenses established by the Government's evidence. *Ruben*, 78 Fed. Reg. at 38,364, 38,385.

Considerations of specific and general deterrence militate in favor of revocation. As discussed, *supra*, the Respondent has made it clear that it feels that it was not so much wrong as misunderstood. Its interpretation of the decision to forego drug seizure on the date of the ISO execution reveals a thought process that leniency connotes lack of trepidation on the part of the Agency. The interests of specific deterrence, therefore, compel the imposition of a sanction.

Likewise, as the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben*, 78 Fed. Reg. at 38,385. To continue the Respondent's registration privileges on the present record would send a message to the regulated community that so long as there is some deficiency in the literature disseminated by state regulatory authorities, or some contextual justification for the failure to identify, resolve, and document dispensing in the face of clear red flags, compliance that might bear some efficiency costs on a busy pharmacy are optional. Even if the Agency discovers legions of improper dispensing events, impactful consequences can be avoided merely by a single training afternoon on a pamphlet, and promising more documentation in the future.

Regarding the egregiousness of the Respondent's conduct, as discussed, *supra*, the evidence demonstrates a staggering volume of improper actions, and it is clear that this Respondent's pharmacists had no interest in monitoring for, identifying, or resolving any indicators of potential controlled substance diversion. The comparative volume of controlled substance purchases uncovered by DEA during the course of its investigation reveals staggering disparities between the amount purchased by the Respondent pharmacy compared to other, similarly-situated enterprises through multiple lenses. [Omitted for relevance.][*S] Mr. Bryce's

[*S] The Respondent, in its Exceptions, objected to the Chief ALJ's finding that "[t]he Respondent's objective appeared to be to inexorably dispense as many controlled substances as possible as fast as possible, while asking as

testimony gave the sense that the Respondent views these charges as the failure of regulators to understand the analysis that was naturally done by the pharmacists on duty, and the venial sin of neglecting to adequately document.[*T] As it happens, this Respondent did fail to exercise the level of care in dispensing and (equally importantly) documenting its dispensing decisions in a manner that would allow a meaningful evaluation by those charged with regulating controlled substances.

A balancing of the statutory public interest factors, coupled with consideration of the Respondent's failure to meaningfully accept responsibility, the absence of record evidence of thoughtful and continuing remedial measures to guard against recurrence, and the Agency's interest in deterrence, supports the conclusion that the Respondent should not continue to be entrusted with a registration.[*U, 160]

Accordingly, the Respondent's DEA COR should be **REVOKED**, and any pending applications for renewal should be **DENIED**.[*V]

---

few questions as possible." Respondent points out that the record evidence does "not reveal the percentage of controlled substances versus non-controls being dispensed at the pharmacy" and that only 15% of Respondent's dispensed prescriptions were controlled substances which was an indication of proper pharmacy practice. Resp Exceptions, at 12. I have omitted the Chief ALJ's finding because it is not relevant to my decision in this matter. This case is about whether or not the prescriptions at issue (which were largely stipulated to) were issued outside the usual course of professional practice such that Respondent's continued registration would be against the public interest. This case is not about Respondent's dispensing of non-controlled substances or about the percentage of controlled versus non-controlled substances dispensed. While positive dispensing experience can be considered under Factor Two, that experience is limited to positive dispensing of controlled substances. For the purpose of this case I have assumed that every prescription, other than those at issue in this case, was lawfully issued. Still, I find that Respondent's dispensing of the prescriptions at issue was sufficiently egregious to support revocation of its registration and my decision is not changed by Respondent's fourth Exception. Resp Exceptions, at 11-13.

[*T] Omitted for brevity.

[*U] Omitted for clarity. I agree with the Chief ALJ's analysis above which focuses on whether or not, in light of the egregiousness of their actions, their equivocal acceptance of responsibility, and their proposed remedial measures, Respondent's current ownership and leadership can currently be entrusted with a registration. And I agree with the Chief ALJ that they cannot. The Chief ALJ went on to evaluate Respondent's historical circumstances, not as irrelevant community impact evidence, but as evidence in support of Respondent's ability to comply with the CSA at some unknown point in the future. Although I credit Respondent for being a long-standing fixture in the community, I do not find that there is any evidence on the record that demonstrates that this is relevant to its compliance with the CSA. As I have stated, I have assumed that all controlled substance prescriptions not at issue in this case were filled legitimately. Although logically the pressure of a long-standing family business could provide some incentive towards integrity, the fact is that the current owners and employees of Respondent pharmacy have not convinced me that this pharmacy can be entrusted with a registration.

[160] Tr. 802-03.

[*V] The Chief ALJ went on to state that if "the Respondent presents the Agency with a comprehensive remedial action plan truly aimed at avoiding recurrence, and communicates credible *indicia* of an unequivocal acceptance of responsibility, it is further recommended that strong consideration be made to favorable consideration of a COR application filed no earlier than two years from the date of the publication of the Agency's final order in the *Federal*

JOHN J. MULROONEY, II

Chief Administrative Law Judge

The Respondent's Exceptions

On July 22, 2020, Respondent filed its Exceptions to the RD. I find that Respondent's six Exceptions[*W] are largely without merit and I have addressed the majority of them in footnotes added to the corresponding parts of the RD above. The remaining Exceptions are addressed herein. While I have made some modifications to the RD based on the Exceptions, none of those changes and none of Respondent's arguments persuaded me to reach a different conclusion than the Chief ALJ in this matter. Therefore, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's continued registration is inconsistent with the public interest, and that revocation is the appropriate sanction.

Exception 3, Regarding Acceptance of Responsibility

Respondent takes exception to the Chief ALJ's finding that Respondent failed to unequivocally accept responsibility for its actions in this case. Resp Exceptions, at 9. First, Respondent explained, the Government took the position that Respondent's acceptance of responsibility in this case was sufficient to make out a *prima facie* case against the Respondent.[*X] Resp Exceptions, at 9 (*citing* Gov Posthearing, at 29-30). Respondent seems to be suggesting that because of the Government's position (which was not relied upon in reaching this decision), I am estopped from finding that Respondent's acceptance of responsibility was not

---

Register." RD, at 67. This recommendation, which seems to be related to the analysis in *supra* n.*U, is too theoretical to include in my final decision, and I do not find that such inclusion is warranted. Any new application in the future would be appropriately evaluated on its own merits, to include Respondent pharmacy's behavior in the intervening timeframe. *See Robert L. Doughtery, M.D.,* 76 Fed. Reg. 16,823, 16,835 (2011) (stating that when determining whether to grant an application where misconduct has already been proven, "DEA has long held that the paramount issue is not how much time has elapsed since his unlawful conduct, but rather, whether during that time Respondent has learned from past mistakes and has determined that he would handle controlled substances properly if entrusted with a new registration" (cleaned up)).

[*W] The exceptions are numbered 1-5, then 7, skipping 6.

[*X] I note that in its Posthearing, the Government seems to have first set forth the evidence it produced to establish its *prima facie* case and then argued, in the alternative, that the *prima facie* case was also met through Respondent's admission. Gov Posthearing, at 21-30.

unequivocal. This argument is unconvincing. In enforcement actions, it is my responsibility to determine whether registrants can be entrusted with a registration and my decision is not bound by an in-the-alternative[*Y] argument presented in a Posthearing Brief. Furthermore, DEA decisions have long established that once the Government has made a *prima facie* case establishing one or more grounds for revocation, I review the evidence and argument Respondent submitted to determine whether or not it has presented "sufficient mitigating evidence to assure the Administrator that [it] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988)). Contrary to Respondent's position, DEA decisions have frequently sanctioned registrants who have stipulated to the full extent of the violations in the Government's *prima facie* case based on DEA's inability to entrust them with a registration in the face of egregious violations of law. *See William Ralph Kincaid, M.D.*, 86 Fed. Reg. 40,636 (2021); *Robert Wayne Locklear*, 86 Fed. Reg. 33,738 (2021); *Jeffrey Stein, M.D.,* 86 Fed. Reg. 46,968 (2019). Next, Respondent argued that the Chief ALJ used the Respondent's explanation of "how it came to be in the position of dispensing these prescriptions" and identification of "instances where it appeared that a claim was being made that was not supported by the facts" against Respondent in determining that Respondent did not unequivocally accept responsibility. Resp Exceptions, at 9-10. The two specific factual references that the Respondent states should not have been weighed against its acceptance of responsibility were that the "Louisiana Board of Pharmacy failed to provide any guidance for its pharmacists regarding 'red flags'" and that "literally millions of prescriptions for [an opiate and a benzodiazepine] were being issued by doctors in the United States every year." *Id.*

I recognize that Respondent has every right to present its case and defend its actions in this matter. However, the agency has long considered statements that are aimed at minimizing

[*Y] The Government also argued that Respondent failed to unequivocally accept responsibility, and Respondent is certainly not suggesting that I be bound by that argument. Gov Posthearing, at 2.

the egregiousness of its conduct to weigh against a finding of acceptance of full responsibility. *See Ronald Lynch, M.D.*, 75 Fed. Reg. 78,745, 78,754 (2010) (Respondent did not accept responsibility noting that he "repeatedly attempted to minimize his [egregious] misconduct"; *see also Michael White, M.D.*, 79 Fed. Reg. 62,957, 62,967 (2014) (finding that Respondent's "acceptance of responsibility was tenuous at best" and that he "minimized the severity of his misconduct by suggesting that he thinks the requirements for prescribing Phentermine are too strict."). The Agency does not bar explanations or rationale as to why the misconduct might have occurred, as long as the acceptance of responsibility is unequivocal and credible, *see Michele L. Martinho, M.D.*, 86 Fed. Reg. 24,012, 24,020 (2021), but the Agency analyzes such acceptance on a case-by-case basis and the crucial aspect of a Respondent's acceptance of responsibility is that it demonstrate to me that it can be entrusted with a registration—that it will not repeat the egregious behavior that occurred.

Here, Respondent through its two witnesses repeatedly made general statements claiming full acceptance of responsibility. For example, Mr. Vicellio testified, "[b]efore we [did not] have [written policies and procedures] and . . . [t]hat is on me, and I do apologize." Tr. 837. Mr. Bryce testified "we 100 percent acknowledge our failure on our . . . corresponding responsibility and we are dedicated, devoted, going overboard, as a matter of fact, because I can guarantee you [there is] no pharmacy in Louisiana that we are aware of or that we even gather you could find that is doing the level of documentation and fulfilling their corresponding responsibilities like we are." Tr. 990-91. However, when the testimony more narrowly focused on the specific deficiencies at issue, it became clear that Respondent was minimizing the extent of its misconduct as the Chief ALJ set forth fully in his decision. *See supra* at The Respondent's Case. Mr. Bryce was particularly unapologetic for the Respondent's failures with regard to accepting alternating payment methods (a cost-saving and an insurance issue), doctor shopping (different specialists prescribe for different ailments), and in some cases trinity prescribing (other pharmacies are still filling these drugs and the FDA never really called a "hard stop").

Respondent did not convince me that it believed that these red flags were indicators of potential diversion that needed serious consideration and proper resolution, and minimized the potential harmful consequences of its actions by stating that the FDA never put a "hard stop" on prescribing the trinity cocktail and it is still being prescribed. In this case, the Respondent's comments regarding red flags demonstrate a lack of full understanding of the extent of its wrongdoing. If I believed that it had demonstrated a complete understanding of its misconduct and understood and accepted the potential for harm that it caused, I would be less concerned about its future compliance. *See Robert Wayne Locklear, M.D.,* 86 Fed. Reg. 33,738, 33,745 (2021) (finding that a respondent's inability to understand the full consequences of his actions weighed against a finding of acceptance of responsibility). As it stands, I was not convinced that Respondent had fully and unequivocally accepted responsibility for its actions. I recognize that Respondent put policies in place that it believes will better identify these potential red flags. Correcting unlawful behavior and practices is very important to establish acceptance of responsibility; however, conceding wrongdoing is critical to reestablishing trust with the Agency. *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62,316, 62,346 (2012), *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,801 (2015). I agree with the Chief ALJ's finding that Respondent failed to unequivocally accept responsibility for its actions in this case.

Exception 2, Regarding Remedial Measures

Where a respondent has not credibly accepted responsibility for its misconduct, I am not required to consider evidence of remedial measures. *See Jones Total Health Care Pharmacy, L.L.C.,* 81 Fed. Reg. 79,202-03. Even if Respondent's acceptance of responsibility for his wrongdoing had been sufficient such that I would consider remedial measures, Respondent has not offered adequate remedial measures here to assure me that I can entrust it with a registration. *See Carol Hippenmeyer, M.D.*, 86 Fed. Reg. 33,748, 33,773 (2021). And if Respondent had offered adequate remedial measures to assure me under other circumstances, my sanctions analysis in this case would still have supported revocation as a sanction. This is because

remedial measures, when considered, are only one of several elements that I evaluate when determining how to exercise my discretionary authority to sanction a registrant.[*Z] If, following that analysis, I am not confident that I can entrust a respondent with the weighty responsibility of maintaining a registration, then I can only find that revocation is an appropriate sanction.

Respondent takes exception to the Chief ALJ's finding that Respondent's remedial measures, namely new policies and procedures, were not sufficient to prevent the recurrence of future CSA violations. Respondent advances this argument from several different angles. First, Respondent claims that there was no "evidence challenging the facial validity of these procedures." Resp Exceptions, at 6. Respondent claims that no "government witness addressed the content of the new procedures," "no evidence was offered to show [what] a set of procedures that have been declared sufficient might look like," and that "the ALJ effectively acted as his own witness in making the subject determination regarding the new procedures." *Id.* at 6-8. Respondent has offered no support for its proposition that I am required to accept its proposed policies and procedures as "facially valid" or that I am required to receive counter evidence regarding the efficacy of its proposed remedial measures. Where the Government has established a *prima facie* case for revocation of a registrant's COR, the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Med. Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008). Here, the Respondent has not presented convincing evidence that I can entrust it with a registration.

Next, Respondent argues, the Chief ALJ erred by speculating as to whether or not the proposed remedial measures would be effective because, "[p]redictions [are not] needed when actual facts are available." Resp Exceptions, at 8. The "facts," which Respondent claims were

---

[*Z] "While the CSA establishes parameters for issuing and terminating registrations, the final registration-related decision, such as granting or denying a registration, and continuing, suspending, or revoking a registration, is left to the reviewable discretion of the Attorney General. 21 U.S.C. §§ 823 and 824 (using the word "may" in provisions to confer discretion on the Attorney General regarding the granting, denying, continuing, suspending, and revoking of practitioner registrations)." *See Frank Joseph Stirlacci M.D.*, 85 Fed. Reg. 45,229, n.18 (2019).

not considered by the ALJ, are that Respondent has "invit[ed] the agency to check out the operations at Medical Pharmacy West," because an investigation would capture whether or not "the new procedures were . . . effectively preventing prescriptions from being filled despite these unresolved red flags." *Id.* Respondent has not provided any support for the notion that DEA's lack of an inspection is proof of the legality of a pharmacy's operation. It is clear that "the agency has discretion regarding whether to bring an enforcement action." *See Ester Mark, M.D.*, 86 Fed. Reg. 16,760, 16,762 (2021) (respondent argued that a time lapse in the investigation and the renewal of her registration during the investigation did not align with the DEA being concerned about her prescribing behavior); (*citing Stirlacci*, 85 Fed. Reg. at 45,236). I sincerely hope, as Respondent contests, that Respondent's sister pharmacy is complying with the law as the Agency will continue to regulate that pharmacy's controlled substances registration; however, after numerous, egregious violations of federal and state law were proven, it was incumbent on the Respondent pharmacy to present the evidence required to demonstrate that its remedial measures were adequate.

Finally, Respondent argues that Mr. Bryce, who was tendered as an expert in the practice of pharmacy in Louisiana, offered uncontroverted testimony that the new policies and procedures "were designed to address the red flags at issue in the case." Resp Exceptions, at 9. Respondent goes on to suggest that I am bound by an uncontradicted opinion of an expert. *Id.* However, Mr. Bryce's testimony on the matter was:

> Q: And the new policies and procedures adopted by Medical Pharmacy West that will go into effect at the pharmacy, designed to attempt to resolve, to handle those red flags and provide a set means of doing so in the future?
> A: Yes, sir. They're designed to provide guidance without any question as to how we are going to handle the red flag and the documentation as such, that they are to be resolved.

Tr. 1050. This testimony appears to be fact testimony explaining what goals Mr. Bryce intended to accomplish when he drafted the new policies. This does not appear to be expert testimony opining as to whether or not the procedures are sufficient to ensure that any prescriptions issued pursuant to policy will be in compliance with the CSA. Even if

Mr. Bryce did intend to testify to the latter, I must consider a witness's credibility in determining what weight to give the testimony. Here, I am not convinced that Mr. Bryce fully understands Respondent's corresponding responsibility under the CSA[*AA] such that I would credit his opinions on the requirements necessary to comply with the CSA.

Additionally, in assessing remedial measures, the Agency must consider its mission in preventing the diversion and misuse of controlled substances and the feasibility of monitoring and enforcing such measures. DEA budgets for approximately 2000 Diversion positions involved in regulating more than 1.9 million registrants overall. *See* DEA FY2022 Budget Request available at https://www.justice.gov/jmd/page/file/1398361/download. Ensuring that a registrant is trustworthy to comply with all relevant aspects of the CSA without constant oversight is crucial to the Agency's ability to complete its mission of preventing diversion within such a large regulated population. *See Jeffrey Stein, M.D.*, 84 Fed. Reg. at 46,974.

Most importantly, the fact remains that, following my sanctions analysis, I am not confident that I can entrust Respondent with the weighty responsibility of maintaining a registration. If I cannot entrust Respondent to implement its proposed remedial measures, then it does not matter whether the measures themselves would adequately address the misconduct. This is why generally I do not consider remedial measures without first establishing an adequate acceptance of responsibility. I need to be confident that the policies will be followed, and I do not have such confidence that would persuade me to place the burden on the Agency whose trust Respondent broke to monitor its compliance with its remedial measures. *See Kaniz Khan Jaffery*, 85 Fed. Reg. 45,667, 45,690 (2020) (finding that respondent hid behind rote diversion controls without

[*AA] For example, as the Chief ALJ set forth in *supra* n. 124, rather than having in-depth, ongoing training on how to spot and resolve red flags and verify the legitimacy of prescriptions, Respondent decided they would no longer dispense, carisoprodol, a legal controlled substance. Tr. 982. While this remedial measure may prevent illegitimate prescriptions of carisoprodol from being dispensed, it does not fill me with confidence that Respondent fully understands the requirements of its corresponding responsibility. Additionally, Respondent's minimization of the severity of the potential dangers of prescribing the trinity cocktail by stating that it is still being frequently filled do not demonstrate a complete understanding of the misconduct that occurred.

legitimately attending to and documenting red flags). Due to the extent and egregiousness of Respondent's misconduct, its failure to adequately accept responsibility, Respondent has not given me reassurance that it can be entrusted with a registration. *See Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988) (describing revocation as a remedial measure "based upon the public interest and the necessity to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration."). Accordingly, I reject Respondent's Exceptions and affirm the RD's conclusion that Respondent's registration should be revoked.

ORDER

Pursuant to 28 CFR § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a) and 21 U.S.C. § 823(f), I hereby revoke DEA Certificate of Registration No. AL3398117 issued to Medical Pharmacy. Pursuant to 28 CFR § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a) and 21 U.S.C. § 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of Medical Pharmacy for registration in Louisiana. This Order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Anne Milgram,
Administrator.

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Medical Pharmacy**	**Docket No. 20-04**

APPENDIX TO THE RECOMMENDED DECISION

The following dispensing events were established by the mutual stipulation of the parties.

Patient CH

The Government's evidence established the following dispensing events with respect to Patient CH:

Dispensing Event	**Date**	**Medications**	**Source**
CH1	9/12/2017	Carisoprodol 350 mg, 120 tablets	Stip. 3(a)
CH2	9/12/2017	Alprazolam 1 mg, 90 tablets	Stip. 3(b)
CH3	9/12/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 3(c)
CH4	9/12/2017	Oxycodone-Acetaminophen 10	Stip. 3(d)

		mg/325 mg, 30 tablets	

Patient JMB

The Government's evidence established the following dispensing events with respect to Patient JMB:

Dispensing Event	**Date**	**Medications**	**Source**
JMB1	6/05/2017	Hydromorphone 8 mg, 120 tablets	Stip. 4(a)
JMB2	6/05/2017	Alprazolam 1 mg, 60 tablets	Stip. 4(b)
JMB3	6/05/2017	Carisoprodol 350 mg, 120 tablets	Stip. 4(c)
JMB4	6/05/2017	Morphine SO4 ER 30 mg, 90 tablets	Stip. 4(d)
JMB5	7/05/2017	Hydromorphone 8 mg, 120 tablets	Stip. 4(h)
JMB6	7/05/2017	Alprazolam 1 mg, 60 tablets	Stip. 4(e)
JMB7	7/05/2017	Carisoprodol 350 mg, 120 tablets	Stip. 4(g)
JMB8	7/05/2017	Morphine SO4 ER 30 mg, 90 tablets	Stip. 4(f)
JMB9	9/14/2017	Alprazolam 1 mg, 60 tablets	Stip. 4(i)

JMB10	9/27/2017	Morphine SO4 ER 30 mg, 30 tablets	Stip. 4(j)
JMB11	9/27/2017	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(k)
JMB12	9/27/2017	Carisoprodol 350 mg, 120 tablets	Stip. 4(l)
JMB13	9/27/2017	Hydromorphone 8 mg, 120 tablets	Stip. 4(m)
JMB14	10/27/2017	Carisoprodol 350 mg, 120 tablets	Stip. 4(n)
JMB15	10/27/2017	Hydromorphone 8 mg, 120 tablets	Stip. 4(o)
JMB16	12/20/2017	Carisoprodol 350 mg, 120 tablets	Stip. 4(p)
JMB17	12/20/2017	Alprazolam 1 mg, 50 tablets	Stip. 4(q)
JMB18	12/20/2017	Hydromorphone 8 mg, 120 tablets	Stip. 4(r)
JMB19	12/21/2017	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(s)
JMB20	8/16/2018	Alprazolam 1 mg, 60 tablets	Stip. 4(t)
JMB21	8/30/2018	Hydromorphone 8 mg, 120 tablets	Stip. 4(u)

JMB22	8/30/2018	Carisoprodol 350 mg, 120 tablets	Stip. 4(v)
JMB23	9/10/2018	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(w)
JMB24	9/21/2018	Alprazolam 1 mg, 60 tablets	Stip. 4(x)
JMB25	9/27/2018	Carisoprodol 350 mg, 120 tablets	Stip. 4(y)
JMB26	9/27/2018	Hydromorphone 8 mg, 120 tablets	Stip. 4(z)
JMB27	10/15/2018	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(aa)
JMB28	10/24/2018	Carisoprodol 350 mg, 120 tablets	Stip. 4(bb)
JMB29	10/24/2018	Hydromorphone 8 mg, 120 tablets	Stip. 4(cc)
JMB30	11/13/2018	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(dd)
JMB31	11/27/2018	Hydromorphone 8 mg, 120 tablets	Stip. 4(ee)
JMB32	11/27/2018	Carisoprodol 350 mg, 120 tablets	Stip. 4(ff)
JMB33	11/29/2018	Alprazolam 1 mg, 60 tablets	Stip. 4(gg)

JMB34	12/24/2018	Carisoprodol 350 mg, 120 tablets	Stip. 4(hh)
JMB35	12/24/2018	Hydromorphone 8 mg, 120 tablets	Stip. 4(ii)
JMB36	12/28/2018	Alprazolam 1 mg, 60 tablets	Stip. 4(jj)
JMB37	1/08/2019	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(kk)
JMB38	1/22/2019	Hydromorphone 8 mg, 120 tablets	Stip. 4(ll)
JMB39	1/22/2019	Carisoprodol 350 mg, 120 tablets	Stip. 4(mm)
JMB40	2/08/2019	Alprazolam 1 mg, 60 tablets	Stip. 4(nn)
JMB41	2/08/2019	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(oo)
JMB42	2/19/2019	Carisoprodol 350 mg, 120 tablets	Stip. 4(pp)
JMB43	2/19/2019	Hydromorphone 8 mg, 120 tablets	Stip. 4(qq)
JMB44	7/01/2019	Morphine SO4 ER 30 mg, 60 tablets	Stip. 4(rr)
JMB45	7/08/2019	Carisoprodol 350 mg, 120 tablets	Stip. 4(ss)

JMB46	7/08/2019	Hydromorphone 8 mg, 120 tablets	Stip. 4(tt)
JMB47	8/05/2019	Hydromorphone 8 mg, 120 tablets	Stip. 4(uu)
JMB48	8/05/2019	Carisoprodol 350 mg, 120 tablets	Stip. 4(vv)
JMB49	8/20/2019	Alprazolam 1 mg, 60 tablets	Stip. 4(ww)
JMB50	8/27/2019	Hydromorphone 8 mg, 120 tablets	Stip. 4(xx)
JMB51	8/27/2019	Carisoprodol 350 mg, 120 tablets	Stip. 4(yy)

Patient TD

The Government's evidence established the following dispensing events with respect to Patient TD:

Dispensing Event	**Date**	**Medications**	**Source**
TD1	7/13/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets	Stip. 5(a)
TD2	8/08/2017	Clonazepam 0.5 mg, 60 tablets	Stip. 5(b)
TD3	8/08/2017	Carisoprodol 350 mg, 60 tablets	Stip. 5(c)

TD4	8/12/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets	Stip. 5(d)
TD5	7/11/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets	Stip. 5(e)
TD6	7/18/2018	Clonazepam 0.5 mg, 60 tablets	Stip. 5(f)
TD7	7/18/2018	Carisoprodol 350 mg, 60 tablets	Stip. 5(g)

Patient DG

The Government's evidence established the following dispensing events with respect to Patient DG:

Dispensing Event	**Date**	**Medications**	**Source**
DG1	2/10/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(a)
DG2	2/10/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(b)
DG3	2/21/2017	Diazepam 10 mg, 60 tablets	Stip. 6(c)

DG4	3/09/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(d)
DG5	3/09/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(e)
DG6	3/21/2017	Diazepam 10 mg, 60 tablets	Stip. 6(f)
DG7	4/06/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(g)
DG8	4/06/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(h)
DG9	4/26/2017	Diazepam 10 mg, 60 tablets	Stip. 6(i)
DG10	5/04/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(j)
DG11	5/04/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(k)
DG12	5/30/2017	Diazepam 10 mg, 60 tablets	Stip. 6(l)

DG13	6/01/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(m)
DG14	6/01/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(n)
DG15	6/29/2017	Diazepam 10 mg, 60 tablets	Stip. 6(o)
DG16	6/29/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(p)
DG17	6/29/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(q)
DG18	7/27/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(r)
DG19	7/27/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(s)
DG20	7/28/2017	Diazepam 10 mg, 60 tablets	Stip. 6(t)
DG21	8/23/2017	Diazepam 10 mg, 60 tablets	Stip. 6(u)

DG22	8/24/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(v)
DG23	8/27/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(w)
DG24	9/21/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(x)
DG25	9/21/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(y)
DG26	9/25/2017	Diazepam 10 mg, 60 tablets	Stip. 6(z)
DG27	11/16/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(aa)
DG28	11/16/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(bb)
DG29	11/20/2017	Diazepam 10 mg, 60 tablets	Stip. 6(cc)
DG30	12/14/2017	Hydrocodone-Acetaminophen 10	Stip. 6(dd)

		mg/325 mg, 120 tablets	
DG31	12/14/2017	Carisoprodol 350 mg, 30 tablets	Stip. 6(ee)
DG32	12/14/2017	Diazepam 10 mg, 60 tablets	Stip. 6(ff)
DG33	1/12/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(gg)
DG34	1/12/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(hh)
DG35	1/24/2018	Diazepam 10 mg, 60 tablets	Stip. 6(ii)
DG36	2/09/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(jj)
DG37	2/09/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(kk)
DG38	2/21/2018	Diazepam 10 mg, 60 tablets	Stip. 6(ll)
DG39	3/09/2018	Hydrocodone-Acetaminophen 10	Stip. 6(mm)

		mg/325 mg, 120 tablets	
DG40	3/09/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(nn)
DG41	3/26/2018	Diazepam 10 mg, 60 tablets	Stip. 6(oo)
DG42	6/06/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(pp)
DG43	6/06/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(qq)
DG44	6/14/2018	Diazepam 10 mg, 60 tablets	Stip. 6(rr)
DG45	7/05/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(ss)
DG46	7/05/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(tt)
DG47	7/16/2018	Diazepam 10 mg, 60 tablets	Stip. 6(uu)
DG48	8/02/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(vv)

DG49	8/02/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(ww)
DG50	8/13/2018	Diazepam 10 mg, 60 tablets	Stip. 6(xx)
DG51	8/30/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(yy)
DG52	8/30/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(zz)
DG53	9/08/2018	Diazepam 10 mg, 60 tablets	Stip. 6(aaa)
DG54	10/26/2018	Carisoprodol 350 mg, 30 tablets	Stip. 6(bbb)
DG55	10/26/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 6(ccc)
DG56	11/06/2018	Diazepam 10 mg, 60 tablets	Stip. 6(ddd)

Patient JH

The Government's evidence established the following dispensing events with respect to Patient JH:

Dispensing Event	Date	Medications	Source
JH1	2/07/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 45 tablets	Stip. 7(a)
JH2	2/07/2017	Diazepam 10 mg, 18 tablets	Stip. 7(b)
JH3	2/07/2017	Zolpidem Tartrate 10 mg, 30 tablets	Stip. 7(c)
JH4	2/09/2017	Carisoprodol 350, 90 tablets	Stip. 7(d)
JH5	7/13/2017	Diazepam 10 mg, 90 tablets	Stip. 7(e)
JH6	7/13/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 40 tablets	Stip. 7(f)
JH7	7/13/2017	Carisoprodol 350, 120 tablets	Stip. 7(g)
JH8	7/31/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 40 tablets	Stip. 7(h)
JH9	8/11/2017	Diazepam 10 mg, 90 tablets	Stip. 7(i)

JH10	8/11/2017	Carisoprodol 350, 120 tablets	Stip. 7(j)
JH11	9/29/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 7(k)
JH12	10/10/2017	Carisoprodol 350, 120 tablets	Stip. 7(l)
JH13	10/11/2017	Diazepam 10 mg, 90 tablets	Stip. 7(m)
JH14	10/26/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 7(n)
JH15	4/26/2018	Carisoprodol 350, 120 tablets	Stip. 7(o)
JH16	4/26/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 7(p)
JH17	4/26/2018	Diazepam 10 mg, 35 tablets	Stip. 7(q)
JH18	5/24/2018	Hydrocodone-Acetaminophen 10	Stip. 7(r)

		mg/325 mg, 90 tablets	
JH19	5/24/2018	Carisoprodol 350, 120 tablets	Stip. 7(s)
JH20	5/24/2018	Diazepam 10 mg, 35 tablets	Stip. 7(t)
JH21	9/20/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 7(u)
JH22	9/20/2018	Carisoprodol 350, 120 tablets	Stip. 7(v)
JH23	9/20/2018	Diazepam 10 mg, 35 tablets	Stip. 7(w)
JH24	10/18/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 7(x)
JH25	10/18/2018	Carisoprodol 350, 120 tablets	Stip. 7(y)
JH26	10/18/2018	Diazepam 10 mg, 35 tablets	Stip. 7(z)

Patient RI

The Government's evidence established the following dispensing events with respect to Patient RI:

Dispensing Event	Date	Medications	Source
RI1	8/17/2017	Alprazolam 1 mg, 120 tablets	Stip. 8(a)
RI2	8/25/2017	Zolpidem Tartrate 10 mg, 30 tablets	Stip. 8(b)
RI3	8/25/2017	Carisoprodol 350 mg, 30 tablets	Stip. 8(c)
RI4	8/25/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(d)
RI5	9/11/2017	Alprazolam 1 mg, 120 tablets	Stip. 8(e)
RI6	9/25/2017	Carisoprodol 350 mg, 30 tablets	Stip. 8(f)
RI7	9/25/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(g)
RI8	10/12/2017	Alprazolam 1 mg, 120 tablets	Stip. 8(h)
RI9	10/25/2017	Carisoprodol 350 mg, 30 tablets	Stip. 8(i)
RI10	10/25/2017	Oxycodone-Acetaminophen 10	Stip. 8(j)

		mg/325 mg, 30 tablets	
RI11	11/13/2017	Zolpidem Tartrate 10 mg, 30 tablets	Stip. 8(k)
RI12	11/13/2017	Alprazolam 1 mg, 120 tablets	Stip. 8(l)
RI13	11/24/2017	Carisoprodol 350 mg, 30 tablets	Stip. 8(m)
RI14	11/24/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(n)
RI15	12/09/2017	Zolpidem Tartrate 10 mg, 30 tablets	Stip. 8(o)
RI16	12/13/2017	Alprazolam 1 mg, 120 tablets	Stip. 8(p)
RI17	12/23/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(q)
RI18	12/27/2017	Carisoprodol 350 mg, 30 tablets	Stip. 8(r)
RI19	8/15/2018	Alprazolam 1 mg, 90 tablets	Stip. 8(s)

RI20	8/24/2018	Carisoprodol 350 mg, 30 tablets	Stip. 8(t)
RI21	8/24/2018	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(u)
RI22	11/08/2018	Alprazolam 1 mg, 90 tablets	Stip. 8(v)
RI23	11/23/2018	Zolpidem Tartrate 10 mg, 30 tablets	Stip. 8(w)
RI24	11/24/2018	Carisoprodol 350 mg, 30 tablets	Stip. 8(x)
RI25	11/24/2018	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(y)
RI26	12/06/2018	Alprazolam 1 mg, 90 tablets	Stip. 8(z)
RI27	12/24/2018	Oxycodone-Acetaminophen 10 mg/325 mg, 30 tablets	Stip. 8(aaa)
RI28	12/24/2018	Hydrocodone-Acetaminophen	Stip. 8(bbb)

		5mg/325 mg, 10 tablets	
RI29	12/24/2018	Carisoprodol 350 mg, 30 tablets	Stip. 8(ccc)
RI30	1/04/2019	Alprazolam 1 mg, 90 tablets	Stip. 8(ddd)

Patient JB

The Government's evidence established the following dispensing events with respect to Patient JB:

Dispensing Event	**Date**	**Medications**	**Source**
JB1	7/02/2019	Dextroamphetamine-Amphetamine 20 mg, 90 tablets	Stip. 9(a)
JB2	7/02/2019	Alprazolam 0.5 mg, 60 tablets	Stip. 9(b)
JB3	7/02/2019	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 9(c)

Patient PW

The Government's evidence established the following dispensing events with respect to Patient PW:

Dispensing Event	**Date**	**Medications**	**Source**

PW1	4/04/2019	Alprazolam 0.5 mg, 60 tablets	Stip. 10(a)
PW2	4/04/2019	Hydrocodone-Acetaminophen 10 mg.325 mg, 30 tablets	Stip. 10(b)
PW3	8/01/2019	Alprazolam 0.5 mg, 60 tablets	Stip. 10(c)
PW4	8/01/2019	Hydrocodone-Acetaminophen 10 mg.325 mg, 30 tablets	Stip. 10(d)
PW5	8/29/2019	Alprazolam 0.5 mg, 60 tablets	Stip. 10(e)
PW6	8/29/2019	Hydrocodone-Acetaminophen 10 mg.325 mg, 30 tablets	Stip. 10(f)

Patient LH

The Government's evidence established the following dispensing events with respect to Patient LH:

Dispensing Event	**Date**	**Medications**	**Source**
LH1	6/14/2017	Alprazolam 1mg, 360 tablets	Stip. 11(a)

LH2	6/22/2017	Dextroamphetamine-Amphetamine 30 mg, 30 tablets	Stip. 11(b)
LH3	6/22/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 20 tablets	Stip. 11(c)

Patient AP

The Government's evidence established the following dispensing events with respect to Patient AP:

Dispensing Event	**Date**	**Medications**	**Source**
AP1	8/02/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 25 tablets	Stip. 12(a)
AP2	8/02/2017	Zolpidem Tartrate 10 mg, 30 tablets	Stip. 12(b)

Patient MA

The Government's evidence established the following dispensing events with respect to Patient MA:

Dispensing Event	**Date**	**Medications**	**Source**

MA1	10/12/2017	Alprazolam 1 mg, 30 tablets	Stip. 13(a)
MA2	10/12/2017	Dextroamphetamine-Amphetamine 30 mg, 60 tablets	Stip. 13(b)
MA3	10/12/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 13(c)

Patient BB

The Government's evidence established the following dispensing events with respect to Patient BB:

Dispensing Event	**Date**	**Medications**	**Source**
BB1	10/19/2017	Alprazolam 1 mg, 90 tablets	Stip. 14(a)
BB2	10/19/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 14(b)
BB3	1/11/2017	Alprazolam 0.5 mg, 2 tablets	Stip. 14(c)
BB4	1/11/2017	Diazepam 10 mg, 2 tablets	Stip. 14(d)

BB5	1/12/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 14(e)
BB6	2/8/2017	Alprazolam 0.5 mg, 2 tablets	Stip. 14(f)
BB7	2/8/2017	Diazepam 10 mg, 2 tablets	Stip. 14(g)
BB8	2/10/2017	Alprazolam 0.5 mg, 60 tablets	Stip. 14(h)
BB9	2/10/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 14(i)
BB10	3/9/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 14(j)
BB11	3/9/2017	Alprazolam 0.5 mg, 60 tablets	Stip. 14(k)
BB12	5/4/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 14(l)

Patient TD

The Government's evidence established the following dispensing events with respect to Patient TD:

Dispensing Event	Date	Medications	Source
TD1	3/07/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 180 tablets	Stip. 15(a)
TD2	3/07/2018	Clonazepam 0.5 mg, 60 tablets	Stip. 15(b)

Patient LD

The Government's evidence established the following dispensing events with respect to Patient LD:

Dispensing Event	Date	Medications	Source
LD1	8/19/2019	Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 16(a)
LD2	8/19/2019	Lorazepam 0.5 mg, 60 tablets	Stip. 16(b)
LD3	8/19/2019	Morphine SO4 ER 30 mg, 60 tablets	Stip. 16(c)

Patient RW

The Government's evidence established the following dispensing events with respect to Patient RW:

Dispensing Event	Date	Medications	Source
RW1	8/12/2019	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 17(a)
RW2	8/12/2019	Diazepam 5 mg, 30 tablets	Stip. 17(b)
RW3	9/09/2019	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 17(c)
RW4	9/09/2019	Diazepam 5 mg, 30 tablets	Stip. 17(d)

Patient LC

The Government's evidence established the following dispensing events with respect to Patient LC:

Dispensing Event	Date	Medications	Source
LC1	3/21/2019	Oxycodone-Acetaminophen 7.5 mg/325 mg, 14 tablets	Stip. 18(a)

LC2	3/21/2019	Oxycodone-Acetaminophen 7.5 mg/325 mg, 16 tablets	Stip. 18(b)

Patient KW

The Government's evidence established the following dispensing events with respect to Patient KW:

Dispensing Event	**Date**	**Medications**	**Source**
KW1	4/16/2019	Alprazolam 0.25 mg, 60 tablets	Stip. 19(a)
KW2	4/16/2019	Dextroamphetamine-Amphetamine 20 mg, 90 tablets	Stip. 19(b)

Patient DM

The Government's evidence established the following dispensing events with respect to Patient DM:

Dispensing Event	**Date**	**Medications**	**Source**
DM1	6/08/2017	Alprazolam 1 mg, 60 tablets	Stip. 20(a)
DM2	6/08/2017	Dextroamphetamine-Amphetamine, 60 tablets	Stip. 20(b)

Patient KS

The Government's evidence established the following dispensing events with respect to Patient KS:

Dispensing Event	Date	Medications	Source
KS1	6/26/2017	Dextroamphetamine-Amphetamine 30 mg, 60 tablets	Stip. 21(a)
KS2	6/26/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 21(b)

Patient PB

The Government's evidence established the following dispensing events with respect to Patient PB:

Dispensing Event	Date	Medications	Source
PB1	6/26/2019	Methadone 10 mg, 60 tablets	Stip. 22(a)
PB2	6/26/2019	Oxycodone-Acetaminophen	Stip. 22(b)

Patient CS

The Government's evidence established the following dispensing events with respect to Patient CS:

Dispensing Event	Date	Medications	Source

CS1	6/11/2019	Oxycodone 30 mg, 90 tablets	Stip. 23(a)
CS2	7/09/2019	Oxycodone 30 mg, 90 tablets	Stip. 23(b)

Patient SN

The Government's evidence established the following dispensing events with respect to Patient SN:

Dispensing Event	**Date**	**Medications**	**Source**
SN1	6/05/2019	Hydrocodone-Acetaminophen 7.5 mg/325 mg, 30 tablets	Stip. 24(a)
SN2	6/19/2019	Hydrocodone-Acetaminophen 7.5 mg/325 mg, 30 tablets	Stip. 24(b)

Patient DF

The Government's evidence established the following dispensing events with respect to Patient DF:

Dispensing Event	**Date**	**Medications**	**Source**
DF1	6/04/2019	Alprazolam 0.5 mg, 120 tablets	Stip. 26(a)

DF2	6/04/2019	Dextroamphetamine-Amphetamine 30 mg, 60 tablets	Stip. 26(b)
DF3	6/04/2019	Butalbital-Acetaminophen-Caffeine 50 mg/325 mg/40 mg, 60 tablets	Stip. 26(c)

Patient DL

The Government's evidence established the following dispensing events with respect to Patient DL:

Dispensing Event	**Date**	**Medications**	**Source**
DL1	8/09/2017	Diazepam 10 mg, 90 tablets	Stip. 27(a)
DL2	8/09/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 27(b)

Patient ML

The Government's evidence established the following dispensing events with respect to Patient ML:

Dispensing Event	**Date**	**Medications**	**Source**
ML1	8/02/2017	Diazepam 10 mg, 45 tablets	Stip. 28(a)

Patient KC

The Government's evidence established the following dispensing events with respect to Patient KC:

Dispensing Event	Date	Medications	Source
KC1	10/09/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 75 tablets	Stip. 29(a)
KC2	10/09/2017	Alprazolam 1 mg, 60 tablets	Stip. 29(b)

Patient GC

The Government's evidence established the following dispensing events with respect to Patient GC:

Dispensing Event	Date	Medications	Source
GC1	10/10/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 30(a)
GC2	10/10/2017	Alprazolam 1 mg, 90 tabelts	Stip. 30(b)

Patient VM

The Government's evidence established the following dispensing events with respect to Patient VM:

Dispensing Event	Date	Medications	Source
VM1	10/20/2017	Hydrocodone-Acetaminophen 10 mg.325 mg, 120 tablets	Stip. 31(a)
VM2	10/20/2017	Alprazolam 1 mg, 60 tablets	Stip. 31(b)

Patient PR

The Government's evidence established the following dispensing events with respect to Patient PR:

Dispensing Event	Date	Medications	Source
PR1	10/24/2017	Hydrocodone-Acetaminophen 10 mg.325 mg, 112 tablets	Stip. 25(a)
PR2	6/13/2019	Hydrocodone-Acetaminophen 10 mg.325 mg, 112 tablets	Stip. 25(b)

Patient AG

The Government's evidence established the following dispensing events with respect to Patient AG:

Dispensing Event	Date	Medications	Source

AG1	9/06/2016	Oxycodone 15 mg, 90 tablets	Stip. 32(a)
AG2	6/27/2019	Oxycodone 15 mg, 120 tablets	Stip. 32(b)
AG3	7/24/2019	Oxycodone 15 mg, 120 tablets	Stip. 32(c)
AG4	8/22/2019	Oxycodone 15 mg, 120 tablets	Stip. 32(d)

Patient TB

The Government's evidence established the following dispensing events with respect to Patient TB:

Dispensing Event	**Date**	**Medications**	**Source(s)**
TB1	5/22/2017	Oxycodone 15 mg, 90 tablets	Stip. 33(a); Gov't Ex 46
TB2	6/25/2018	Oxycodone 15 mg, 60 tablets	Stip. 33(b)
TB3	7/09/2018	Oxycodone 15 mg, 60 tablets	Stip. 33(c)
TB4	7/23/2018	Oxycodone 15 mg, 60 tablets	Stip. 33(d)

Patient KR

The Government's evidence established the following dispensing events with respect to Patient KR:

Dispensing Event	Date	Medications	Source
KR1	4/09/2019	Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 34(a)
KR2	8/04/2018	Oxycodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 34(b)

Patient LW

The Government's evidence established the following dispensing events with respect to Patient LW:

Dispensing Event	Date	Medications	Source
LW1	7/27/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 35(a)
LW2	7/27/2017	Alprazolam 1 mg, 90 tablets	Stip. 35(b)
LW3	7/27/2017	Dextroamphetamine-Amphetamine 20 mg, 60 tablets	Stip. 35(c)
LW4	7/27/2017	Phentermine 37.5 mg, 30 tablets	Stip. 35(d)

Patient KJ

The Government's evidence established the following dispensing events with respect to Patient KJ:

Dispensing Event	Date	Medications	Source
KJ1	5/21/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 36(a)
KJ2	7/21/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 36(b)
KJ3	11/19/2018	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 36(c)

Patient VE

The Government's evidence established the following dispensing events with respect to Patient VE:

Dispensing Event	Date	Medications	Source
VE1	5/22/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 37

Patient TP

The Government's evidence established the following dispensing events with respect to Patient TP:

Dispensing Event	Date	Medications	Source
TP1	5/22/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 38

Patient IJ

The Government's evidence established the following dispensing events with respect to Patient IJ:

Dispensing Event	Date	Medications	Source
IJ1	5/23/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 39

Patient RS

The Government's evidence established the following dispensing events with respect to Patient RS:

Dispensing Event	Date	Medications	Source
RS1	5/26/2017	Hydrocodone-Acetaminophen 10	Stip. 40

		mg/325 mg, 120 tablets	

Patient RW

The Government's evidence established the following dispensing events with respect to Patient RW:

Dispensing Event	Date	Medications	Source
RW1	6/01/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 120 tablets	Stip. 41

Patient JW

The Government's evidence established the following dispensing events with respect to Patient JW:

Dispensing Event	Date	Medications	Source
JW1	5/12/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 42

Patient MS

The Government's evidence established the following dispensing events with respect to Patient MS:

Dispensing Event	Date	Medications	Source
MS1	5/12/2017	Oxycodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 43

Patient PF

The Government's evidence established the following dispensing events with respect to Patient PF:

Dispensing Event	Date	Medications	Source
PF1	5/22/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 44

Patient DW

The Government's evidence established the following dispensing events with respect to Patient DW:

Dispensing Event	Date	Medications	Source

DW1	5/22/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 90 tablets	Stip. 45

Patient KD

The Government's evidence established the following dispensing events with respect to Patient KD:

Dispensing Event	**Date**	**Medications**	**Source**
KD1	5/04/2017	Hydrocodone-Acetaminophen 10 mg/325 mg, 60 tablets	Stip. 46

[FR Doc. 2021-27416 Filed: 12/17/2021 8:45 am; Publication Date: 12/20/2021]